



## **GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING**

### **DECISION N° GB/15/2024**

#### **on the approval of the Consolidated Annual Activity Report 2023**

THE GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING (hereafter “Global Health EDCTP3 JU”),

Having regard to Council Regulation (EU) No 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014 (hereafter “the Founding Regulation”), in particular Article 17(2)(p) and 26(1) thereof,

Having regard to the Financial Rules of the Global Health EDCTP3 JU<sup>1</sup>, and in particular Article 23 thereof,

Having regard to the advice of the Scientific Committee of 18-19 April 2024 on the scientific achievements to be described in the Consolidated Annual Activity Report 2023,

#### **WHEREAS:**

- (1) On 29 May 2024 the Executive Director of the Global Health EDCTP3 JU has submitted for assessment and approval to the Governing Board the draft Consolidated Annual Activity Report 2023.
- (2) The Scientific Committee in its Annual Report 2023 has advised on the scientific achievements to be described in the Consolidated Annual Activity Report 2023.
- (3) The Governing Board of the Global Health EDCTP3 JU shall assess and approve the Consolidated Annual Activity Report 2023.
- (4) On 14 June 2024, the Executive Director of the Global Health EDCTP3 JU has submitted to the Governing Board the final Consolidated Annual Activity Report 2023, which includes the revised estimated amount of in-kind contributions to additional activities for the years 2022 and 2023 and previous years and the final annual accounts.

**HAS ADOPTED THIS DECISION:**

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<sup>1</sup> Governing Board decision GB/22/2022

**Article 1**

The Consolidated Annual Activity Report 2023 of the Global Health EDCTP3 JU, including information on the corresponding expenditure and contributions from members other than the Union, the declaration of the Executive Director on reasonable assurance and the assessment by the Governing Board, annexed to this Decision, is hereby approved.

**Article 2**

The Consolidated Annual Activity Report 2023, together with its assessment by the Governing Board, shall be sent by the Executive Director to the European Court of Auditors, the European Parliament and the Council by 1st July 2024.

The Executive Director shall make the Consolidated Annual Activity Report 2023 publicly available on the Global Health EDCTP3's website.

**Article 3**

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 27 June 2024.

*For the Global Health EDCTP3 Joint Undertaking Governing Board*

Qualified electronic signature by:  
LENA IRENE MARGARETA NORSTEDT  
Date: 2024-06-27 20:28:45 +02:00

Irene Norstedt

*Chairperson of the Governing Board*

Annex:

1. Consolidated Annual Activity Report 2023 of the Global Health EDCTP3 JU.

*Annex to GB decision N° GH-EDCTP3-GB/15/2024*

# GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING

## CONSOLIDATED

## ANNUAL ACTIVITY REPORT 2023

In accordance with Article 26 of Council Regulation (EU) 2021/2085 of 19 November 2021 and with Article 23 of the Financial Rules of the Global Health EDCTP3 JU.

The Consolidated Annual Activity Report (CAAR) will be made publicly available after its approval by the Governing Board.

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## FACTSHEET

<b>Name of the JU</b>	Global Health EDCTP3 Joint Undertaking (hereinafter “Global Health EDCTP3 JU”)
<b>Objectives</b>	<p>The general objectives of the Global Health EDCTP3 JU are:</p> <p>a) to contribute to the reduction of the socioeconomic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies;</p> <p>(b) to contribute to the increase of health security in sub-Saharan Africa and globally by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases.</p>
<b>Legal Basis</b>	<p>Article 187 of the Treaty on the Functioning of the European Union</p> <p>Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014</p> <p>(hereinafter “Single Basic Act – SBA” or “Founding Regulation”)</p>
<b>Executive Director</b>	Dr Michael Makanga was appointed Executive Director (ED) as of 16 November 2023 <sup>1</sup>
<b>Governing Board</b>	<p>Chairperson: Dr Henning Gädeke (EDCTP Association)</p> <p>Vice-Chairperson: Irene Norstedt (European Commission, RTD)</p> <p>12 members in total: 6 from the European Commission and 6 from the EDCTP Association</p> <p>More information on the Governing Board (GB) can be found <a href="#">here</a>.</p>

<sup>1</sup> <https://globalhealth-edctp3.eu/news/dr-michael-makanga-named-new-executive-director-global-health-edctp3-joint-undertaking>

<b>Other bodies</b>	<p><u>Scientific Committee (SC)</u>: 18 members</p> <p>Chairperson: Professor John Gyapong</p> <p>Vice-Chairperson: Professor Marleen Temmerman</p> <p><u>Stakeholders Group (SG)</u>: 33 members</p> <p>Chairperson: Dr. Neeraj Mistry</p> <p>Vice-Chairperson: Dr. Christine Nabiryo</p>
<b>Staff number</b>	<p>Number of employees in the JU Programme Office (incl. Executive Director) at the time of the drafting of this CAAR<sup>2</sup>:</p> <p>23 statutory staff (17 temporary agents and 6 contract agents)</p>
<b>Final adopted budget 2023<sup>3</sup></b>	<p>Commitment appropriations: EUR 137 557 312</p> <p>Payment appropriations: EUR 51 224 384<sup>4</sup></p>
<b>Budget implementation after the financial autonomy: from 23 November 2023 to 31 December 2023<sup>5</sup></b>	<p><u>Commitment appropriations</u></p> <p>Total consumption:</p> <p>EUR 135 848 575 – Percentage spent on total: 100%</p> <p>Title 1 – EUR 541 615 – Percentage spent on total: 71%</p> <p>Title 2 – EUR 585 906 – Percentage spent on total: 68%</p> <p>Title 3 – EUR 134 721 055 – Percentage spent on total: 100%</p> <p><u>Payment appropriations</u></p> <p>Total consumption:</p> <p>EUR 1 019 792 – Percentage spent on total: 47%</p> <p>Title 1 – EUR 183 370 – Percentage spent on total: 24%</p> <p>Title 2 – EUR 317 900 – Percentage spent on total: 40%</p> <p>Title 3 – EUR 518 522 – Percentage spent on total: 83%</p>
<b>Grants</b>	<p>In 2023, 27 grants were signed for a total value of EUR 100 137 623,75</p>

<sup>2</sup> As per the template received by the Common Services, the number of employees is at the time of the drafting of the CAAR.

<sup>3</sup> Total budget includes operational budget (used for funding selected projects) & administrative (used for funding the JU Programme Office activities).

<sup>4</sup> The second and last amendment of the annual budget 2023 was approved by the Governing Board on 18 December 2023.

<sup>5</sup> Budget implementation before the financial autonomy:  
Commitment appropriations total consumption: Running costs: EUR 1113 307 (41%) and Operational costs: EUR 554 924 (0%)  
Payment appropriations total consumption: Running costs: EUR 1182 181 (43%) and Operational costs: EUR 47 863 626 (90%)



<b>Strategic Research &amp; Innovation Agenda</b>	<p>The Strategic Research and Innovation Agenda (SRIA) was adopted by the Governing Board on 12 January 2022, by decision GB/04/2022.</p> <p>An internal survey has been launched within the Stakeholders Group to discuss the need for a SRIA Update. 76% of respondents considered that the SRIA needed a slight update. Discussions have been ongoing on the nature of the updates, which will be jointly discussed with the Scientific Committee of the JU and the Programme Office.</p>
<b>Call implementation</b>	<p>Number of calls launched in 2023: 2 (Involving five single-stage topics and two two-stage topics)</p> <p>Number of proposals submitted: 178 (99 under single-stage call, 79 under two-stage call)</p> <p>Number of eligible proposals: 165 in total (91 under single-stage call and 74 under stage 1 of two-stage call)</p> <p>Number of proposals granted: 27</p> <p>Number of global project portfolio as of end of 2023: 28 (1 at the end of 2022 and 27 in 2023)</p>
<b>Participation, including SMEs</b>	<p>Total number of beneficiaries in funded projects: 260 of which:</p> <ul style="list-style-type: none"> <li>- 3% of SMEs and 2 % of EU funding received by those SMEs</li> <li>- 7 % of private for profit/large companies and 3 % of EU funding received by those companies</li> <li>- 65% of non-EU – non-associated members' entities including countries typically with low research capacity (openness)</li> </ul>

## FOREWORD

Dear reader,

It is with pleasure that I present to you the Consolidated Annual Activity Report of the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU).

Building on the previous investments of over EUR 1 billion of the first and second EDCTP programmes, the new EUR 1,6 billion Global Health EDCTP3 programme has reignited the momentum in the fight against infectious diseases. With a fresh investment of over EUR 103 million in its first year of implementation in 2022, 28 new projects are already running.

During the year 2023, we continued supporting key research into infectious diseases, and expanding our activities to ensure a stronger, long-lasting impact. We launched further funding opportunities to grow our portfolio of investments. With a total budget of over EUR 130 million, seven new calls for proposals were launched in 2023 to support activities aiming to tackle the Ebola outbreaks in sub-Saharan Africa, improve women and children's health and improve modes of delivery and uptake of vaccines, among others.

On 16 November, I started my tenure as the new Executive Director and following my appointment, on 23 November, the Global Health EDCTP3 JU became financially autonomous from the European Commission, which had supported the establishment and initial operation of the programme until it achieved the operational capacity to implement its own budget. Moreover, we finalised the institutional setting by establishing the Stakeholders Group, a new body working to provide input on the scientific, strategic and technological priorities to be addressed by the Global Health EDCTP3, as well as ensuring synergies between the partnership and adjacent sectors. These events marked significant milestones and kick-started the new implementation phase of the Global Health EDCTP3 programme.

In December 2023, the Work Programme 2024 was published with over EUR 140 million in funding opportunities, the highest annual budget since the Global Health EDCTP3 JU was established. This annual programme will support a range of activities aimed at tackling diseases such as malaria, HIV/AIDS or Neglected Tropical Diseases (NTDs), as well as building research capacity in Africa through academia-industry fellowships for researchers.

Our investments reflect our ambition to become the leading research partnership on infectious diseases and we expect the new projects supported under these calls for proposals to directly contribute to our objectives.

This ambition was showcased during the Eleventh EDCTP Forum held in Paris. With almost 1 000 participants, this special event allowed us to celebrate the 20th anniversary of EDCTP and highlight the

excellent work carried out by researchers, policy makers and health research stakeholders in the fight against infectious diseases, as well as look forward to the challenges and opportunities ahead.

Moreover, the JU Programme Office continued to grow and to deliver on its core tasks, launching and evaluating calls for proposals, supporting beneficiaries in achieving impressive results and ensuring synergies with like-minded partners, with the overall goals of strengthening the research ecosystems in Africa and Europe and contributing to the fight against infectious diseases globally.

To conclude, I take this opportunity to thank everyone involved in the Global Health EDCTP3 programme, colleagues, beneficiaries, partners and many more, for your efforts and contributions to our common objectives. I look forward to continuing working with you to provide solutions for those who need them most.

**Dr Michael Makanga, Global Health EDCTP3 Joint Undertaking Executive Director.**

## EXECUTIVE SUMMARY

### 1. Introduction

Looking back on the year, 2023 witnessed the full establishment of the Global Health EDCTP3 Joint Undertaking. During this year, core processes and governing bodies were established and galvanised, two Work Programmes for 2023 and 2024 respectively were adopted, their funding opportunities launched, and the first grants were signed, leading to the start of exciting new projects.

Moreover, several initiatives were taken to raise awareness and promote the partnership among the research, innovation and global health stakeholders. This year, which also marked the 20th anniversary of the EDCTP programme since its initial launch in 2003, was concluded on a very positive note with several success stories from the In-Kind Additional Activities (IKAA) of the programme, which are also featured in this report.

### 2. Laying the foundations: Autonomy and governance

In 2023, the Global Health EDCTP3 finalised the establishment of its governance structures and bodies, as well as implemented its financial and administrative frameworks following the financial autonomy from the European Commission in November 2023.

During this year, the Global Health EDCTP3's private co-funder (the EDCTP Association) has grown its sub-Saharan Africa (SSA) members pool from 21 to 28 countries, welcoming Benin, Guinea-Bissau, Liberia, Malawi, Sierra Leone, Somalia, and Zimbabwe, highlighting the value that these countries attribute to international collaboration with the 15 European countries that are part of the EDCTP Association.

This expansion has allowed the Joint Undertaking to further establish itself as the reference funding agency for clinical trial-related research in sub-Saharan Africa (SSA) and as the main opportunity for SSA countries to become global health research and innovation leaders. Moreover, the World Health Organisation (WHO) recognised the exemplary role of this partnership in the ongoing global discussion on clinical research capacity.

Additionally, the Global Health EDCTP3 established its Stakeholders Group (SG) having as a mission to provide input on its scientific, strategic and technological priorities. This group is currently composed of 33 members from key fields in global health, such as academia, industry, civil society organisations and patient representatives. Coordination and collaboration of the SG with the Global Health EDCTP3's other key advisory body, the Scientific Committee (SC) has been established to ensure complementarities and pooling of knowledge. On 7 November 2023, the two groups met for the first time on the side of the EDCTP Forum to lay the foundations of their collaborative work and identify synergies.

### 3. Core business: R&I projects and calls for proposals

#### Running projects

In 2022, the Global Health EDCTP3 published its first Annual Work Programme and funding opportunities. During 2023, the JU Programme Office managed to conclude and sign these grant agreements, as well as subsequently, launch the prefinancing payments, monitor their implementation and support projects when needed.

With a total funding of over EUR 103 million, the first 28 projects funded under the Global Health EDCTP3 signed their grant agreements in 2022 and 2023 and commenced their work during 2023.

Nineteen of these are research and innovation projects implementing clinical trials and other clinical research activities. In particular, the running projects are working on diseases such as malaria, HIV, tuberculosis, as well as Lassa fever, certain Neglected Infectious Diseases (NIDs) alternatively referred to as Neglected Tropical Diseases (NTDs) and antimicrobial resistance (AMR)-related infections.

Nine projects are focusing on coordination and strengthening institutional capacities and the enabling environment for conducting clinical research. For example, five of these projects are working to strengthen regulatory capacity for supporting conduct of clinical trials in SSA.

Importantly, all projects funded under the Global Health EDCTP3 are supporting South-South and South-North collaboration. This is a requirement when applying for funding, as all consortia are obliged to have at least one partner from a European Union member state or country associated to Horizon Europe, and at least one partner from a sub-Saharan African country that is a member of the EDCTP Association.

#### Work Programme 2023 publication and evaluation

On 4 April 2023, the Global Health EDCTP3 published its Work Programme 2023 with EUR 131,90 million in funding opportunities to support research into infectious diseases. This annual programme included different funding opportunities (topics), dividing into single-stage and two-stage topics.

Five of these topics closed submission of proposals on 4 July 2023. Ninety-nine proposals were submitted and 27 proposals were selected for funding with a total budget of EUR 78,2 million. The successful proposals were informed in November 2023 and quickly thereafter started the process of Grant Agreement Preparation (GAP). These projects are expected to start their activities in mid-2024.

Two further topics (total budget of EUR 56 million) were launched under a two-stage procedure. Seventy-nine first-stage proposals were submitted by the first deadline, 28 September 2023. Eligible proposals subsequently underwent expert evaluation that focused on the scientific excellence and expected impact. Thirty-seven proposals were invited to submit their complete research proposal by

3 April 2024, after which the second and final evaluation stage will take place, with the aim to invite proposals for GAP by June 2024.

#### Communication and dissemination

In 2023, communication activities of the Global Health EDCTP3 focused on four main objectives: to establish new communication channels and tools; promote funding opportunities; raise awareness about the partnership; and to promote funded projects and their results.

To achieve these objectives, a new web-presence and social media accounts were launched, where key information about the Joint Undertaking governance, funding opportunities, news, activities and resources is regularly published. Moreover, specific events to promote funding opportunities were organised on 23 March and 12 April 2023 as well as to provide potential applicants with information on the calls for proposals, as well as information on eligibility criteria and other relevant administrative matters.

Importantly, the [Eleventh EDCTP Forum](#) which took place from 7 to 10 November 2023 in Paris provided an excellent opportunity to showcase the work and projects funded under EDCTP1 and EDCTP2, as well as to promote the third iteration of the programme, Global Health EDCTP3.

### **4. Collaboration and coordination: Enhancing impact**

#### Working with the European Commission: Ensuring coordination

Strategic coordination mechanisms with the different Directorate-Generals (DGs) of the European Commission working in health have been established. Under the leadership of DG RTD, a regular Sherpa meeting with the key DGs has been established with the aim to promote knowledge sharing and synergies between the programmes.

An in-depth cooperation has been established with DG INTPA, who has invested over 1 billion in Africa on health-related fields. Monthly coordination meetings have been established for information exchanges, consultation on topic texts, availability of relevant experts and identification of potential synergies or joint calls to be taken forward.

#### Working with the EDCTP Association: In-Kind Additional Activities

In addition to the direct funding attributed by the Global Health EDCTP3 JU Programme Office to eligible organisations carrying out clinical research and other activities, the member countries of the EDCTP Association also align and coordinate their activities in the scope of the programme.

The contribution from the EDCTP Association is predominantly in the form of In-Kind Additional Activities (IKAA), which are mostly multi-annual. For the year 2023, the EDCTP Association submitted a

plan to initiate, through its constituents, additional activities with an estimated value of EUR 86 621 213. This brings the total estimated value of all initiated additional activities by the end of year 2023 to EUR 387 605 543. Additionally, in anticipation of the UK association to Horizon Europe, in December 2023 the EDCTP Association committed to increasing its contribution to the Global Health EDCTP3 by at least EUR 110 122 000 to reach a total contribution of at least EUR 550 million.

Among the activities already reported, several of them are already leveraging major impact on key diseases such as malaria, HIV, tuberculosis and NIDs, as well as on creating and supporting the necessary capacity building activities and networks that support this research.

For example, the Multi-Stage Malaria Vaccine Consortium, MMVC progressed the clinical development of the R21/Matrix-M™ which has culminated in the 2023 WHO recommendation for the use of new malaria vaccine R21/Matrix-M, for the prevention of malaria in children. The R21/Matrix-M malaria vaccine is an easily deployable vaccine and is expected to result in sufficient vaccine supply to benefit all children living in areas where malaria is a public health risk.

Moreover, in December 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA) adopted a positive scientific opinion of the use of Fexinidazole Winthrop as first oral treatment for *Trypanosoma brucei rhodesiense* sleeping sickness. The trial for treatment with Fexinidazole Winthrop in Malawi and Uganda was supported by EDCTP through the HAT-r-ACC consortium with co-financing from several countries through the partnership, Drugs for Neglected Diseases initiative (DNDi). This CHMP opinion paves the way for the update of WHO guidelines on sleeping sickness, as well as the extended indication and distribution of fexinidazole in African countries where *Trypanosoma brucei rhodesiense* is prevalent.

Furthermore, some of the activities supported by these IKAAs have supported the creation of coordination and collaboration networks. The EDCTP2-funded epidemic preparedness networks – ALERRT and PANDORA-ID-NET – have made coordinated efforts to enhance countries' abilities to manage the COVID-19 pandemic. On top of this, the PANDORA ID NET played a critical supportive role in the drafting, consultation and final publishing of the Africa CDC framework for One Health practice in national public health institutions. This is a guiding document supporting One Health implementation that the Africa CDC is using to advise and support African Member States.

#### Working with other partners: Establishing new relationships

In 2023, the Global Health EDCTP3 has established new conversations with nearly a dozen different partners in order to identify potential synergies and promote coordinated responses, in particular with joint calls for proposals for the year 2025.

Moreover, active participation in different global health fora has held a high priority in the programme so as to raise the visibility of the Global Health EDCTP3 and ensure engagement with stakeholders and potential partners. In this respect, the JU Programme Office attended and/or organised sessions at the

3rd Africa Health Research and Innovation Funders Forum (South Africa, August), Grand Challenges Forum (Senegal, October), World Health Summit (Germany, October), the WHO Global Clinical Trials Forum (Switzerland, November) and the International Conference on Public Health in Africa (Zambia, November).

These events have proven key to establish our status as a global public health funder and to initiate discussions with other fundings. For example, at the Grand Challenges meeting held in Dakar (Senegal) in October 2023, the five projects that resulted from the Global Health EDCTP3's first joint call with a collaborating partner, the Bill and Melinda Gates Foundation (BMGF), together with the relevant partners, held their first joint meeting, launching their collaboration with the aim to strengthen genomic epidemiology infrastructure in Africa.

In the global arena, the Global Health EDCTP3 JU participated in the first ever Health Day at COP 28, including the Reaching the Last Mile Forum side-event, where we pledged over EUR 46 million to fight Neglected Tropical Diseases (NTDs) in sub-Saharan Africa.

Moreover, through the EDCTP Africa office, we have ensured that the Global Health EDCTP3 programme maintains its regional presence in Africa. The office and its staff provide an excellent platform and avenue for supporting programme activities best executed from an African location. These include implementing and monitoring capacity developing activities, organising workshops, facilitating dialogue between African and European research entities and other stakeholders, promoting networking activities (South-North and South-South), and overall, increasing the visibility of Global Health EDCTP3.

### Conclusion

In 2023, Global Health EDCTP3 has successfully managed to finalise its set-up as a new Joint Undertaking, as well as implemented its Work Programme, the only of its kind tackling infectious diseases in both Africa and Europe. This new funding model for EDCTP encourages global co-funding and collaboration and, building on the previous programmes, carries the legacy of equitable research partnerships.

The work and results of the first funded projects and the activities carried out under the IKAAs showcase the tangible impact that the partnership is having on the ground, improving health research capacities, and improving the wellbeing of affected populations. In addition, the good response to the calls for proposals launched displays the high level of interest in the partnership and its field of work.

Over the years, EDCTP has managed to establish a true partnership of equals between African and European partners, a key aspect on which we have built on during this past year. By pooling resources of African States, European States, the EU and the private sector, Global Health EDCTP3 has a clear structuring effect, decreasing fragmentation and ensuring efficiency, bringing forward positive contributions to the fight against infectious diseases in SSA and increased health security globally.



# 1. IMPLEMENTATION OF THE ANNUAL WORK PROGRAMME 2023

## 1.1. Key objectives 2023, associated risks and corrective measures

One of the objectives of the JU in 2023 was to successfully award and sign grant agreements from the previous year's calls. In this respect, the evaluation, and awards of funding for all single stage calls (Work Programme 2022) have been finalised and led to the signature of 28 Grant Agreements by the end of 2023 (of which one was signed in 2022 and 27 in 2023).

Taking into consideration that the JU became financially autonomous only in November 2023, adequate measures have been taken to ensure the smooth pre-financing of the newly signed Grant Agreements.

Furthermore, the Global Health EDCTP3 JU's Work Programme 2023 was composed of 7 topics with a budget of over EUR 130 million in funding opportunities to support research into infectious diseases. This funding was used to support:

- Clinical research fellowships (RIA): Single stage calls with a budget of EUR 15 300 000;
- Further funding to successfully finalise clinical trials from EDCTP2, which have been negatively impacted by the COVID-19 pandemic (RIA): Single stage calls with a budget of EUR 14 000 000;
- Implementing research/real life assessments of existing interventions in women and children's health (RIA): Single stage call with a budget of EUR 26 000 000;
- Research to rapidly evaluate interventions on Ebola outbreaks in Africa (RIA): Single Stage, Budget of EUR 11 000 000;
- Strengthening ethics and regulatory capacity (CSA): Single Stage, Budget of EUR 8 000 000;
- Improving modes of delivery, deployment and uptake of vaccines through phase IV/implementation research (RIA): Two stage, Budget of EUR 30 000 000;
- Advancing point-of-care diagnostics to the market through comparative testing. This includes all diseases in scope of Global Health EDCTP3, for example, antimicrobial resistance and emerging diseases (RIA): Two Stage, Budget of EUR 26 000 000.

The evaluation of the first stage of the two-stage call has been conducted successfully and the second stage evaluation is expected in April 2024, with a total of 37 proposals invited to the second stage.

Despite several engagements with potential contributing partners, the novelty of the process for contributing partners has not allowed the fast-enough maturation of collaborations and commitments to financial contributions for the Work Programme 2023. Discussions were maintained and collaborations for the Work Programme 2024 are being explored.

The relevant indicators for each of the Global Health EDCTP3 JU specific objectives are presented in the table below and in Figure 1:

Global Health EDCTP3 JU Objectives	Indicators																										
To advance development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials in SSA	<ul style="list-style-type: none"> <li>- 4 calls launched</li> <li>- 14 projects funded</li> <li>- EUR 52 198 971,68 invested in RIA</li> </ul>																										
To strengthen research and innovation capacity and the national health research systems in SSA for tackling infectious diseases	<ul style="list-style-type: none"> <li>- 2 calls launched</li> <li>- 10 projects funded</li> <li>- EUR 26 024 494,25 invested in CSA and RIA</li> </ul>																										
To facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment	<p>59 IKAA projects planned to be launched in 2023 with estimated total* per country (in EUR):</p> <table> <tr><td>Austria</td><td>750 000</td></tr> <tr><td>Belgium</td><td>2 750 000</td></tr> <tr><td>Ethiopia</td><td>200 000</td></tr> <tr><td>France</td><td>28 653 000</td></tr> <tr><td>Germany</td><td>2 000 000</td></tr> <tr><td>Mali</td><td>321 716</td></tr> <tr><td>Mozambique</td><td>100 000</td></tr> <tr><td>Norway</td><td>300 000</td></tr> <tr><td>Portugal</td><td>440 000</td></tr> <tr><td>South Africa</td><td>1 990 785</td></tr> <tr><td>Spain</td><td>1 413 000</td></tr> <tr><td>Uganda</td><td>12 674 011</td></tr> <tr><td>United Kingdom</td><td>35 028 702</td></tr> </table> <p>*full duration of multi-annual projects <i>Graphic presentation in Figure 2 below.</i></p>	Austria	750 000	Belgium	2 750 000	Ethiopia	200 000	France	28 653 000	Germany	2 000 000	Mali	321 716	Mozambique	100 000	Norway	300 000	Portugal	440 000	South Africa	1 990 785	Spain	1 413 000	Uganda	12 674 011	United Kingdom	35 028 702
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Portugal	440 000																										
South Africa	1 990 785																										
Spain	1 413 000																										
Uganda	12 674 011																										
United Kingdom	35 028 702																										
To strengthen capacity for epidemic preparedness in SSA through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential	<ul style="list-style-type: none"> <li>- 1 call launched</li> <li>- 3 projects funded</li> <li>- EUR 9 356 653,68 invested in RIA &amp; CSA</li> </ul>																										
To promote productive and sustainable networking and partnerships in the area of global health research building North-South and South-South relationships with multiple private and public-sector organisations	<ul style="list-style-type: none"> <li>- 0 of joint calls with Contributing Partners</li> <li>- 1 project co-funded by a Contributing Partner is part of a programme, where the partner BMGF plans to invest EUR 33 million.</li> </ul>																										

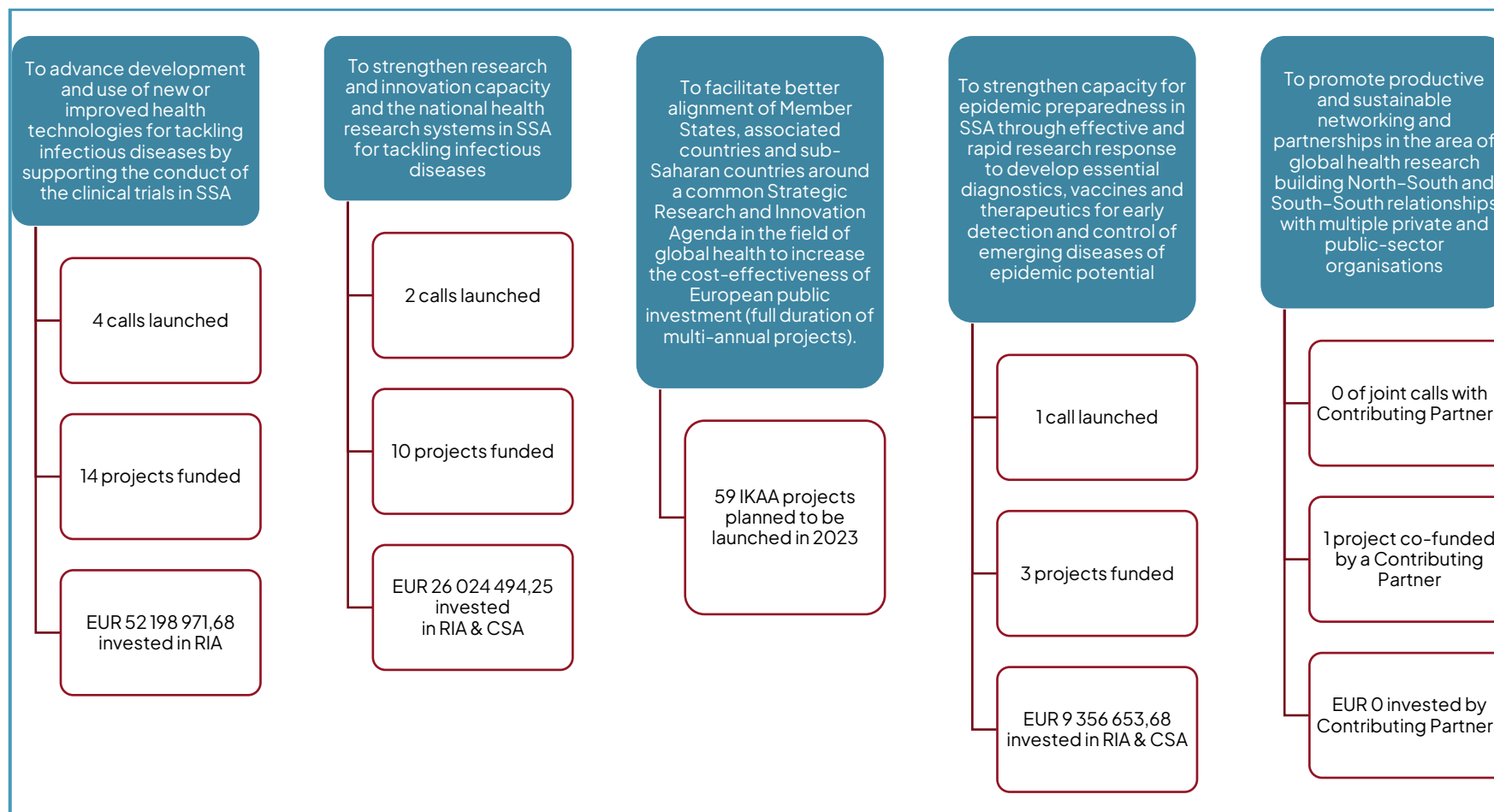


Figure 1: Indicators for each of the Global Health EDCTP3 JU specific objectives

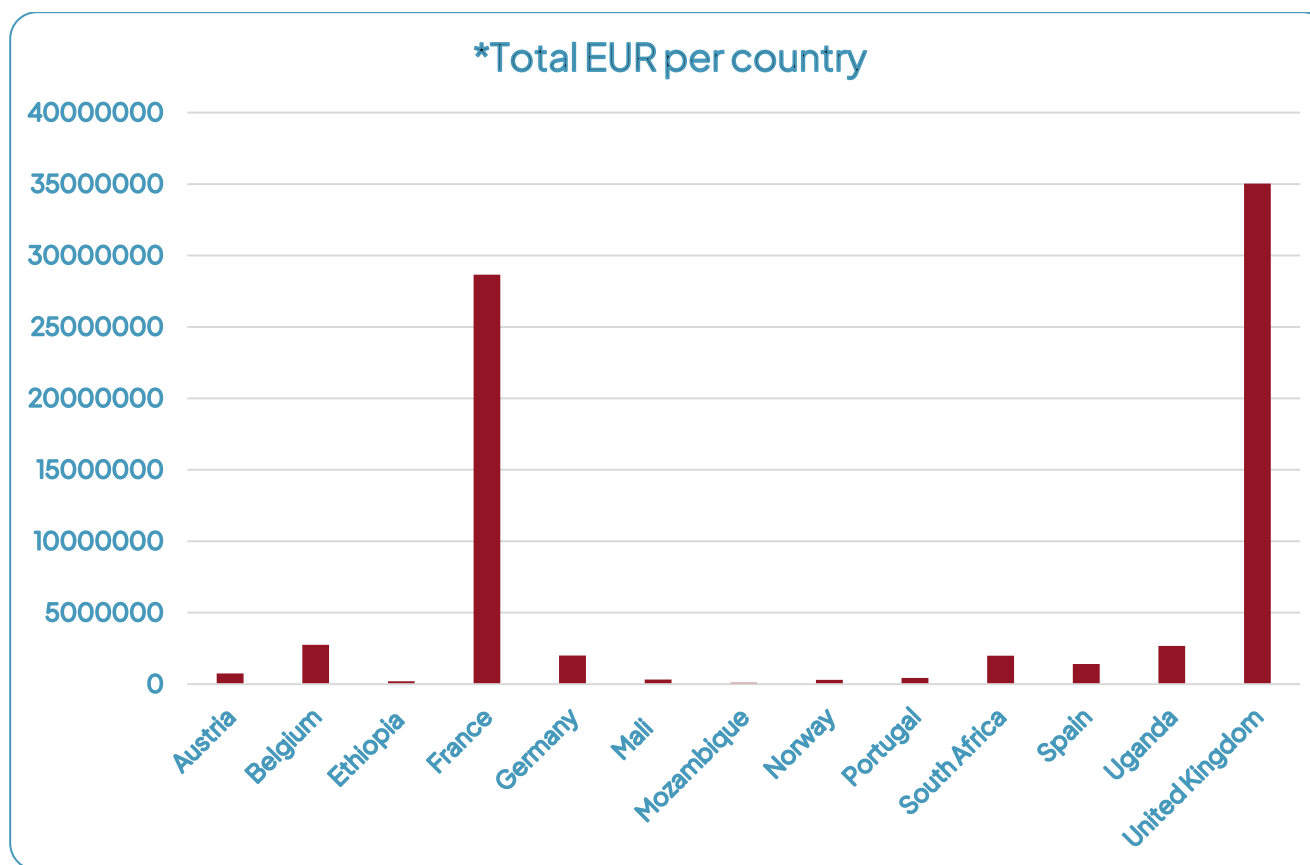


Figure2: 59 IKAA projects planned to be launched in 2023 with estimated total amount per country

## 1.2. Research & Innovation activities/achievements

Call topics from the Work Programmes 2022 and 2023 (partially closed) have generated projects that will potentially lead to scientific and technological achievements. The current projects include grants that are building on the success made through the previous EDCTP programmes. From the Work Programme 2022, the Global Health EDCTP3 JU is supporting 19 research and innovation actions including clinical trials and other clinical research activities conducted by European-African consortia. In addition, under the same Work Programme, the Global Health EDCTP3 JU is supporting 9 projects which focus on coordination and strengthening institutional capacities and the enabling environment for conducting clinical trials and clinical research. Under its Work Programme 2023, the Global Health EDCTP3 JU has invited (in November 2023) 27 proposals for grant preparation. The 27 proposals include 21 for research innovation projects and 6 for coordination and support projects.

## 1.3. Calls for proposals, grant information and other funded actions

Under the Work Programme 2023, two calls for proposals were launched:

- a single-stage call with a total budget of EUR 74 300 000 (HORIZON-JU-GH-EDCTP3-2023-01-01) covering four Research and Innovation Action (RIA) topics and one Coordination and Support Action (CSA) topic;
- a two-stage call with a total budget of EUR 56 000 000 (HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage) covering two Research and Innovation Action (RIA) topics.

Details of the evaluation outcomes and a breakdown of the submitted proposals by participant country and participant type (including SMEs) are presented in Section “1.4. Evaluation procedures and outcomes”.

Five of the topics required applicants to comply with the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe:

- HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials negatively impacted by the COVID-19 pandemic;
- HORIZON-JU-GH-EDCTP3-2023-01-03: Implementation research/real life assessment of existing interventions in women and children’s health;
- HORIZON-JU-GH-EDCTP3-2023-01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa;
- HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research;
- HORIZON-JU-GH-EDCTP3-2023-02-02-two-stage: Advancing point-of-care diagnostics to the market.

The implementation of this provision required the addition of deliverables and additional exploitation obligations in the projects.

Each of the consortia selected for funding from these topics added the following deliverables in their projects:

1. Stewardship plan: Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report.
2. Global access plan: With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.

Also, participants from these projects are subject to the following additional exploitation obligations:

1. Participants must – up to four years after the end of the action – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participant's best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.
2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences – under fair and reasonable conditions – to their results to legal entities that commit to rapidly and broadly exploit the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions.
3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results.
4. For up to four years after the action, the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

## 1.4. Evaluation procedures and outcomes

On 4 April 2023, the Global Health EDCTP3 JU published its 2023 calls for proposals on the Funding & Tenders opportunities portal:

- HORIZON-JU-GH-EDCTP3-2023-01-01: the call opened for submission of proposals on 10 May 2023 with a deadline of 4 July 2023;
- HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage: the call opened for submission of proposals on 27 June 2023 and the first stage closed on 28<sup>th</sup> of September 2023. The second stage opened on 20 December 2023 with a deadline of 3 April 2024.

### HORIZON-JU-GH-EDCTP3-2023-01-01

The call HORIZON-JU-GH-EDCTP3-2023-01-01 covers the following 5 topics and types of action:

Topic ID	Topic name	Types of action	Budget (in EUR)
HORIZON-JU-GH-EDCTP3-2023-01-01	Clinical research fellowships	Research and Innovation Action (RIA)	15 300 000
HORIZON-JU-GH-EDCTP3-2023-01-02	Funding to successfully finalised clinical trials from EDCTP2, which have been negatively impacted by the COVID-19 pandemic	Research and Innovation Action (RIA)	14 000 000
HORIZON-JU-GH-EDCTP3-2023-01-03	Implementing research/real life assessments of existing interventions in women and children's health	Research and Innovation Action (RIA)	26 000 000
HORIZON-JU-GH-EDCTP3-2023-01-04	Research to rapidly evaluate interventions on Ebola outbreaks in Africa	Research and Innovation Action (RIA)	11 000 000
HORIZON-JU-GH-EDCTP3-2023-01-05	Strengthening ethics and regulatory capacity	Coordination and Support Action (CSA)	8 000 000

The call received a total of 99 proposals of which 8 (8,1%) were declared ineligible.

The evaluation for the call HORIZON-JU-GH-EDCTP3-2023-01-01 was carried out between 28 August 2023 and 15 September 2023 by the evaluation committee/panel appointed by the responsible Authorising Officer with the assistance of 85 external experts.

The evaluation committee/panel was composed of external experts.



The external experts were selected in a way to ensure a high level of skills, experience, and knowledge in the areas of the call (including project management, innovation, exploitation, dissemination and communication and financial aspects).

Special attention was given to achieve an appropriately balanced composition (skills, experience, knowledge, geographical diversity, gender, and private-public sector balance) and regular rotation.

As a result, out of the invited 85 experts:

- 52% were women;
- 73% came from universities and public or private research organisations;
- 12% were from private commercial firms;
- 67% were new experts (i.e. experts who have not participated in any EU evaluations over the last three calendar years);
- 60% were brand new experts (i.e. experts who have never participated in any EU evaluation);
- 42% of the experts belonged to the ICPC-ACP-Africa group, 36% to EU Member States, 2% to the Associated Countries group, and the remaining 20% to other countries.

The rotation rules that applied to the Horizon Europe Programme were respected.

The evaluation procedure was also observed by an observer (i.e. independent external expert to advise on the conduct and fairness of the evaluation sessions, the application of the evaluation criteria and ways to improve the processes).

## Briefing

At the start of the evaluation, the evaluators were briefed on applicable rules, process, procedures, evaluation criteria and scope and objectives of the call.

Where appropriate, a special briefing was held for consensus group rapporteurs, remote evaluation and other issues (e.g. ethics).

The briefings emphasised confidentiality requirements and rules on conflict of interests.

All evaluators received the documentation with respect to the Global Health EDCTP3 JU Annual Work Programme and the call for proposal (e.g. call conditions, etc.).

## Evaluation: Award criteria and scoring

The evaluation was made against the award criteria and evaluation rules as set out in the call conditions.

## Individual evaluation

Each proposal was evaluated against the award criteria, independently by at least 5 evaluators.

The evaluators prepared, for each proposal, an individual evaluation report (IER), with comments and scores for each criterion (directly on-line in the Funding & Tenders Portal Electronic Evaluation System).

## Consensus group

The individual evaluators then formed, for each proposal, a consensus group, in order to reach a common view and agree on comments and scores (consensus report).

The evaluation task was planned with an overall agenda that, for each day, listed the consensus meetings taking place, the name of the project officer (PO) in charge, the time of the session, and the links for accessing the Webex platform.

In each consensus meeting, the discussion was led by the rapporteur, who had prepared a draft consensus report (CR) beforehand, based on the individual evaluation forms (IERs) received from the evaluators.

## Panel review

Finally, the evaluation committee/panel examined and compared the consensus reports together, to check on the consistency of their scores and comments and — in case of equal scores — to agree on a priority order.

## Evaluation outcome

A total of 27 proposals were proposed for funding (with 2 of them being promoted from the reserve list of topic 01 and topic 03 respectively).

### Number of proposals by topic

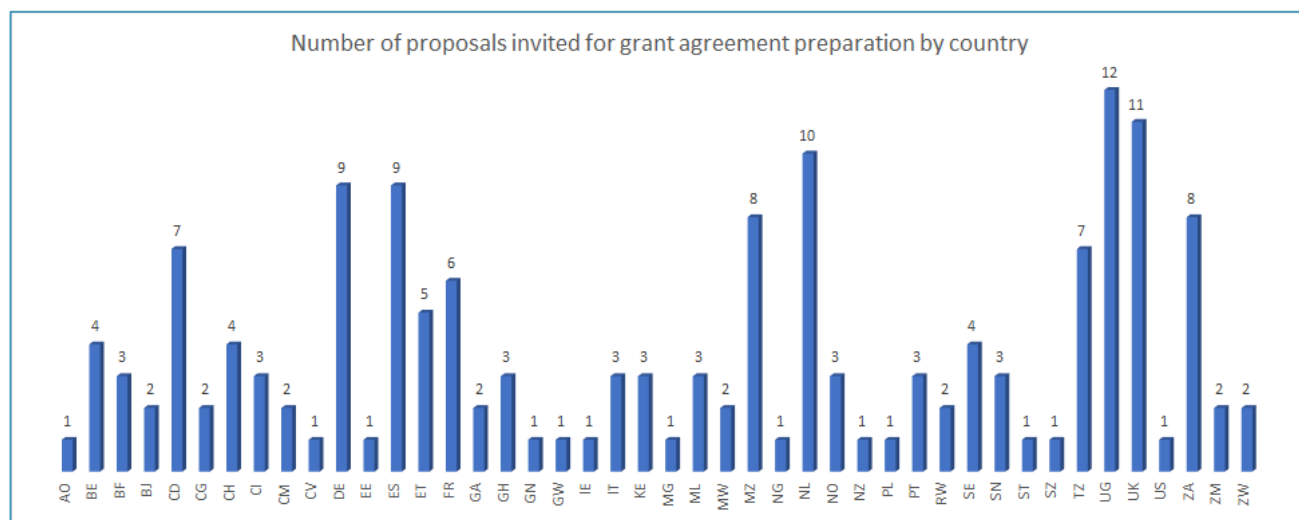
Topic	Number of proposals submitted	Ineligible proposals	Number of proposals evaluated	Proposals invited for grant agreement preparation	Success Rate
HORIZON-JU-GH-EDCTP3-2023-01-01	25	2	23	4	17,39 %
HORIZON-JU-GH-EDCTP3-2023-01-02	18	0	18	8	44,44 %
HORIZON-JU-GH-EDCTP3-2023-01-03	28	2	26	6	23,08 %
HORIZON-JU-GH-EDCTP3-2023-01-04	10	1	9	3	33,33 %
HORIZON-JU-GH-EDCTP3-2023-01-05	18	3	15	6	40,00 %
<b>TOTAL</b>	<b>99</b>	<b>8</b>	<b>91</b>	<b>27</b>	<b>27,47 %</b>

### Grant requested amount by topic

Topic	Proposals invited for grant agreement preparation	Grant requested (in EUR)	Topic budget (in EUR)	Difference (in EUR)
HORIZON-JU-GH-EDCTP3-2023-01-01	4	19 954 665,00	15 300 000,00	-4 654 665,00
HORIZON-JU-GH-EDCTP3-2023-01-02	8	13 646 355,50	14 000 000,00	353 644,50
HORIZON-JU-GH-EDCTP3-2023-01-03	6	29 195 962,50	26 000 000,00	-3 195 962,50
HORIZON-JU-GH-EDCTP3-2023-01-04	3	9 356 653,68	11 000 000,00	1 643 346,32
HORIZON-JU-GH-EDCTP3-2023-01-05	6	6 069 829,25	8 000 000,00	1 930 170,75
<b>Grand Total</b>	<b>27</b>	<b>78 223 465,93</b>	<b>74 300 000,00</b>	<b>-3 923 465,93</b>

The difference has been covered by using the 1 million Euro foreseen for the emergency funding mechanism and by transferring EUR 2 923 466 from administrative cost.

### Number of proposals invited for grant agreement preparation in 2023 for Calls 2022 and 2023 by country



Note: During the reporting year 2023, the UK was not yet associated to Horizon Europe. The figures for Calls 2023 do not include data for the two-stage calls as the evaluations are to be completed during 2024.

### Redress cases

Out of the 99 proposals received, 6 (6%) redress requests were submitted by applicants by mid-January 2024.

### HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage

The HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage call covers the following 2 topics and types of action:

Topic ID	Topic short name	Types of action	Budget (in EUR)
HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage	Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research	Research and Innovation Action (RIA)	30 000 000
HORIZON-JU-GH-EDCTP3-2023-02-02-two-stage	Advancing point-of-care diagnostics to the market	Research and Innovation Action (RIA)	26 000 000

The call received a total of 79 proposals in Stage 1, of which 5 (6,3%) were declared ineligible.

One proposal has been moved from Topic 2 to Topic 1 via the standard Obvious Clerical Error procedure, following agreement from the coordinator.

The evaluation for the HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage call was carried out between 30 October 2023 and 17 November 2023 by the evaluation committee/panel appointed by the responsible Authorising Officer with the assistance of 39 external experts.

The evaluation committee/panel was composed of external experts.

The external experts were selected in a way to ensure a high level of skills, experience, and knowledge in the areas of the call (including project management, innovation, exploitation, dissemination and communication and financial aspects).

Special attention was given to achieve an appropriately balanced composition (skills, experience, knowledge, geographical diversity, gender, and private-public sector balance) and regular rotation.

As a result, out of the invited 39 experts:

- 44% were women;
- 69% came from universities and public or private research organisations;
- 13% were from private commercial firms;
- 48% were new experts (i.e. experts who have not participated in any EU evaluations over the last three calendar years);
- 48% were brand new experts (i.e. experts who have never participated in any EU evaluation);
- 52% of the experts belonged to the ICPC-ACP-Africa group, 33% to EU Member States, 5% to the Associated Countries group, and the remaining 10% to other countries.

The rotation rules that applied to the Horizon Europe programme were respected.

The evaluation procedure was also observed by an observer (i.e. independent external expert) to advise on the conduct and fairness of the evaluation sessions, the application of the evaluation criteria and ways to improve the processes.

## Briefing

At the start of the evaluation, the evaluators were briefed on applicable rules, process, procedures, evaluation criteria and scope and objectives of the call.

The briefings emphasised confidentiality requirements and rules on conflict of interests.

All evaluators received the documentation with respect to the Global Health EDCTP3 JU Annual Work Programme and the call (e.g. call conditions, etc.).

## Evaluation: Award criteria and scoring

The evaluation was made against the award criteria and evaluation rules as set out in the call conditions.

### Individual evaluation

Each proposal was evaluated against the award criteria, independently by at least 3 evaluators. The evaluators prepared, for each proposal, an individual evaluation report (IER), with comments and scores for each criterion (directly on-line in the Funding & Tenders Portal Electronic Evaluation System).

### Consensus group

The individual evaluators then formed, for each proposal, a consensus group, in order to reach a common view and agree on comments and scores (consensus report).

The evaluation task was planned, with an overall agenda that, for each day, listed the consensus meetings taking place, the name of the project officer in charge, the time of the session, and the links for accessing the Webex platform.

In each consensus meeting, the discussion was led by the rapporteur, who had prepared a draft consensus report (CR) beforehand, based on the individual evaluation forms (IERs) received from the evaluators.

### Invitation to Stage 2

In accordance with the requirements set out in the call conditions, the overall thresholds were set at a level that the total requested budget for the proposals admitted to stage 2 is as close as possible to 3 times (but not lower than 2.5 times) the available budget. The thresholds that were applied are the following (per committee/panel):

Topic ID	Topic short name	Budget (in EUR)	Overall threshold applied	Proposals invited to submit in Stage 2	Total requested EU contribution of proposals invited to stage 2 (in EUR)
HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage	Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research	30 000 000	8	16	81 438 999
HORIZON-JU-GH-EDCTP3-2023-02-02-two-stage	Advancing point-of-care diagnostics to the market	26 000 000	9	21	99 547 065

A total of 37 (50%) consortia were invited to submit proposals for Stage 2 of the call HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage on 20 December 2023.

The stage 2 deadline is 03 April 2024 and the evaluation will be carried out in May 2024.

## 1.5. Follow-up activities linked to past calls

In the course of 2023, grant agreements linked to the 2022 calls for proposals were signed. In total proposals, 29 proposals were invited to grant preparation, including 2 proposals submitted by identified beneficiaries [HORIZON-JU-EDCTP3-2022-GH-Epidemiology-IBA and HORIZON-JU-EDCTP3-2022-GH-Africa-IBA], and 27 proposals from the HORIZON-JU-GH-EDCTP3-2022-01 Call. Of the 29 proposals invited to grant preparation, 28 projects were signed, and 1 was terminated at grant preparation phase.

From the 27 grants preparation linked with the HORIZON-JU-GH-EDCTP3-2022-01 Call, 26 were signed in 2023 and 1 was terminated in grant preparation phase. One of the 2 for proposals submitted by identified beneficiaries was signed in 2023, while the other was signed at the end of 2022.

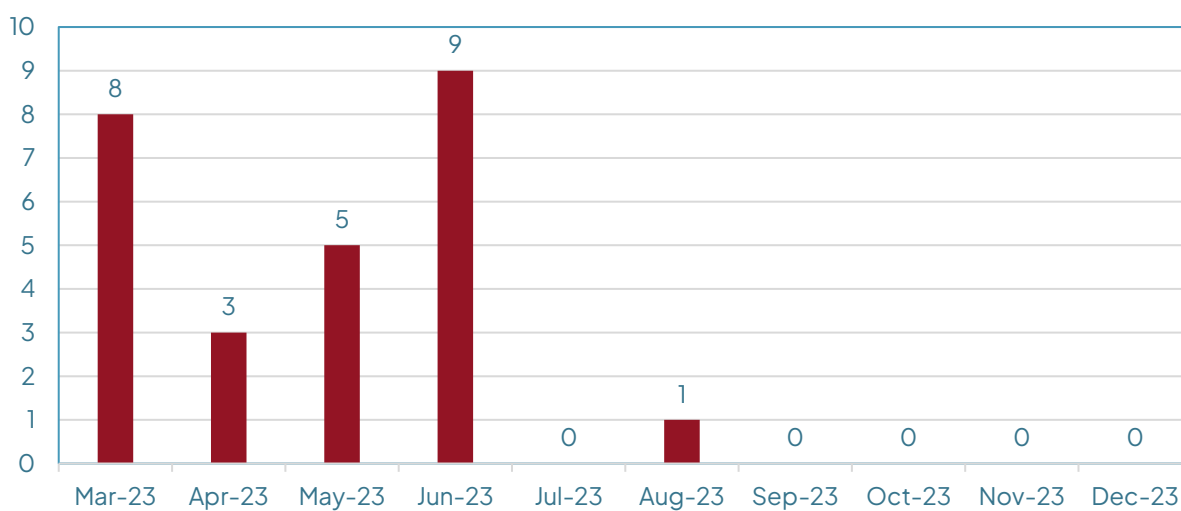
Activities linked to past calls – in this case, linked to the Work Programme 2022 calls – included grant agreement preparations, prefinancing payments to signed grants, monitoring of the newly signed projects, and kick off meetings of projects being initiated.

**Table 1. Signed projects from the HORIZON-JU-GH-EDCTP3-2022-01 Call**

Acronym	Project Id	Grant Agreement signature date	Time to Grant
ACCESSAFRICA2	101103296	28/04/2023	241
BREEDIME	101103217	02/05/2023	245
CTCAN	101103299	02/05/2023	245
Decide-TB	101103283	21/03/2023	203
ECOWAS-RegECs	101103241	01/06/2023	275
EpiGen Ethiopia	101103188	29/06/2023	303
EPiTB	101103281	25/04/2023	238
eWHORM	101103053	02/03/2023	184
GenPath Africa	101103171	28/08/2023	363
GREAT-LIFE	101103059	13/06/2023	287
IMPRIMA	101103213	21/03/2023	203
INTEGRATE	101103204	23/06/2023	297

Acronym	Project Id	Grant Agreement signature date	Time to Grant
MARC SE-Africa	101103076	31/03/2023	213
MOBILE MEN	101103140	22/06/2023	296
NeuroSolve	101103306	27/04/2023	240
ODIN	101103253	02/06/2023	276
PANGenS	101103174	23/06/2023	297
PDMC Saves Lives	101103078	30/05/2023	273
PROMISE-ZERO	101103295	02/03/2023	184
SCALE-IT	101103332	11/05/2023	254
SEARCH II	101103195	06/06/2023	280
SEMAReACT	101103191	07/03/2023	189
SERCEA	101103307	17/05/2023	260
SNIP-AFRICA	101103201	07/06/2023	281
STOP2030	101103089	07/03/2023	189
STROGHAT	101103189	31/03/2023	213

Number of signed grants per month  
Call HORIZON-JU-GH-EDCTP3-2022-01





*Table 2. Signed project from the HORIZON-JU-EDCTP3-2022-GH-Epidemiology-IBA Call*

Acronym	Project Id	Grant Agreement signature date	Time to Grant
NGS4PublicHealth	101104504	09/11/2023	104

*Table 3. Signed project from the HORIZON-JU-EDCTP3-2022-GH-Africa-IBA Call*

Acronym	Project Id	Grant Agreement signature date	Time to Grant
EDCTP Africa Office	101103640	20/12/2022	428

### The EDCTP Africa Office Grant

The EDCTP Africa Office (AO) grant is a three-year (2023-2025) project (maximum grant value of EUR 2 953 000) awarded to the EDCTP Africa Office (located in Cape Town and hosted by the South African Medical Research Council) by the Global Health EDCTP3 Joint Undertaking. This was the first grant to be signed by the JU. The EDCTP Africa Office, from inception, has consistently promoted capacity building in sub-Saharan African countries. As the EDCTP2 programme approaches its end date with reducing administrative budget, the EDCTP AO would not be able to continue providing the same level of capacity building support to sub-Saharan African countries in the foreseeable future. This would increase the risks of not retaining the value of regional presence, and unique human resource skills and experience built in over 20 years. The EDCTP AO grant and the activities it supports send a positive message to the African research community and policy makers that the EDCTP3 programme is truly a balanced African and European partnership. This grant provides an excellent platform and avenue for supporting the implementation of the EDCTP3 programme, including implementing and monitoring capacity developing activities, organising workshops, facilitating dialogue between African and European research entities and other stakeholders promoting networking activities (South-North, South-South), and increasing the visibility of the Global Health EDCTP3 JU.

In the year 2023, through the funding provided under the grant, the EDCTP AO undertook several capacity development and networking activities including:

- Working with partners, including [PREPARED EU](#) and [African Bioethics Initiative](#), to successfully integrate their training plans with the 2024 plans of the World Health Organization African Region Office (WHO-AFRO) [African Vaccine Regulatory Forum \(AVAREF\)](#). Three of these courses will be delivered in 2024 and 2025 training AVAREF regulators on emerging ethics codes for guiding the conduct of clinical trials among vulnerable populations during emergencies and epidemics.

- Facilitated engagements between [Regional Networks of Excellence](#) and other partner initiatives in Africa including with industry.
- A [Fellows Day](#) was held at the Eleventh EDCTP Forum on 7 November 2023 in Paris. The activity involved one session for engagement with all fellows and another focusing on 10 consortia training 150 epi-biostats fellows under a joint training programme of Africa CDC and EDCTP.
- Held 68 virtual and physical interactions with different like-minded partner organisations working on global health in Africa, with the focus of increasing the visibility of the Global Health EDCTP3.
- Brought new African member states into the EDCTP Association. Current membership stands at 28.
- Initiated discussions with WHO-AFRO and [African Union Development Agency-NEPAD](#) (AUDA-NEPAD) with the objective of renewing the Memorandum of Understanding (MoUs), which have expired.

## 1.6. Openness, cooperation, synergies and cross-cutting themes and activities

No exceptions to the open call principle have been launched in 2023 as the JU only launched open calls in 2023.

Strategic orientation with other enterprises has been initiated: coordination mechanisms and synergies between the European Commission programmes in health have been established: DG RTD has established regular Sherpa meetings with key DGs involved in health. Information exchange on ongoing relevant programmes and identification of cooperation and synergies could be taken forward.

More in-depth cooperation has been established with DG INTPA, investing over 1 billion in Africa in health. Monthly coordination meetings have been established for information exchanges, consultation on topic texts, availability of relevant experts and identification of potential synergies or joint calls to be taken forward. In addition, coordination with support services (Health Advisory Service and the TESS for the support of the Team Europe Initiative on manufacturing in Africa) has been put in place.

Consultations have taken place with IHI JU and other JUs on topics, processes, governance and contributing partners for increased harmonisation.

Synergies are sought at national level through the coordination with Team Europe Initiatives and at regional level, through a coordination with the Africa CDC, the ECDC and EMA.

Requests for coordination with EU Delegations have been submitted.

## 1.7. Progress against Key Impact Pathways and JU's Key Performance Indicators

The Global Health EDCTP3 JU launched 3 calls for proposals in 2022, with a total of 28 projects awarded grants and signed by the end of 2023, and an EU contribution of EUR 103 090 623,75 complemented by EUR 15 565 115,04 co-funded via partnerships. No projects funded by the Global Health EDCTP3 JU have yet concluded.

### 1.7.1. Progress against General Horizon Europe Key Impact Pathways Indicators

The European Commission IT central service is developing a centrally managed dashboard to collect the micro-data behind the Key Impact Pathway indicators (KIPs) for all parts of the Programme. The 28 projects funded by the end of 2023 include a total of 201 researchers. The Global Health EDCTP3 JU will report on further General Horizon Europe KIPs as soon as the Global Health EDCTP3-related data will be fully available and exportable from the central dashboard.

### 1.7.2. Progress against HE Common JUs Key Performance Indicators

In 2023, the Global Health EDCTP3 JU established its autonomy as the reference funding agency for clinical trial-related research in Sub-Saharan Africa (SSA) and as the main opportunity for SSA countries to become global health research and innovation leaders. Since its inception, the Global Health EDCTP3 JU's private co-funder (the EDCTP Association) has grown its SSA members pool from 21 to 28 countries in 2023, welcoming Benin, Guinea-Bissau, Liberia, Malawi, Sierra Leone, Somalia, and Zimbabwe. This clearly highlights the value that these countries attribute to international collaboration with the 15 European countries that are part of the EDCTP Association.

Up to the end of 2023 and after only one year of activity, the Global Health EDCTP3 JU has funded projects involving institutions from 43 different countries, including 11 EU member states and 28 African Union countries, with three calls for proposals worth a total of EUR 121 611 226,67 funding, of which EUR 103 090 623,75 funded via Horizon Europe. One of these calls was launched in partnership with the Bill & Melinda Gates foundation that will contribute up to EUR 33 000 000 to allow the knowledge expansion on genomic epidemiology in Sub-Saharan Africa.

The internationality of the Global Health EDCTP3 JU is reflected in its stakeholder group, composed of 33 organisation members, of which 8 are based in European Union countries, 15 in ICPC-ACP-Africa states and 10 in others.

### 1.7.3. Progress against JU-specific Key Performance Indicators

Key Impact Pathways (KIPs) data are not available for 2022 and 2023 as no project has yet ended.

The Programme Office consulted the Scientific Committee, in their advisory role, in regard to the JU-specific KPIs according to Article 19(4)(o) of the SBA.

KPIs have been categorised in three main groups: Input/Resources; Outcomes; and Impacts. In general, the scientific experts mentioned the need to define the frequency of measurement as well as adequately reflect the complementarity with partners in the KPIs as the Global Health EDCTP3 acts in a specific scientific framework, and this comparison would allow to assess both internal and external coherency. The current version of these KPIs will be further refined and detailed with the Scientific Committee. The below intermediate version reflects the first inputs (**in bold**) gathered during the 5th Scientific Committee meeting, which took place on 18 and 19 April 2024.

	Input/Resources	Outcomes	Impact
JU specific KPIs	<ul style="list-style-type: none"> <li>Investment in R&amp;I in SSA.</li> <li>Investment in CSA in SSA.</li> <li>Investment in training and career development actions in SSA.</li> <li>Investment per disease area.</li> <li>Investment per intervention type.</li> <li>Research and finance management training</li> <li><b>Set of KPIs reflecting diversity and distribution of funded research entities (including non-traditional).</b></li> <li><b>Set of KPIs reflecting processes and activities (e.g., number of evaluations processes).</b></li> <li>Investment in coordination and partnership building.</li> <li>Investment in networks of excellence.</li> <li>Investment in community engagement.</li> </ul>	<ul style="list-style-type: none"> <li>High quality research on new or improved health technologies conducted and disseminated.</li> <li>Uptake of health technologies in local settings.</li> <li>New Digital Health initiatives in SSA.</li> <li>New Health-related climate change initiatives in SSA.</li> <li>Strategic Partnerships built.</li> <li>Local community involved (e.g., awareness campaign reach, knowledge improvement).</li> <li>Sustained and increased training and capacity development in SSA.</li> <li>Increased research and finance management capacity.</li> <li><b>Increased partnerships and interaction with the health services on the ground and the ministries of health for the planning and strategy.</b></li> <li><b>Increased partnerships and involvement of all interested parties: research, academia, industry, including end users (need to train and educate them in line with the cultural diversity).</b></li> <li><b>Set of KPIs on good partnership practices between European and African teams (e.g. authorship).</b></li> <li><b>Outcome of investments in partnership building and community engagement.</b></li> </ul>	<ul style="list-style-type: none"> <li>Increased health security in SSA.</li> <li>Increased monitoring and awareness of infectious diseases in SSA.</li> <li>Increased ethics and regulatory capacity in SSA.</li> <li><b>Better translation and better utilisation of the outputs of the funded projects.</b></li> <li><b>Improvement of equity in terms of gender, language and regional differences.</b></li> <li><b>Improvement of public health outcomes in the disease areas covered by GH EDCTP3 in field (e.g. of KPIs, incidence and prevalence rates, infection rates, AMR rates, vaccination coverage, mortality, hospitalization...).</b></li> <li><b>Increased local and International funding for research coupled with excellent research and finance management practices.</b></li> </ul>

## 1.8. Dissemination and information about project results

The year 2023 marked the start of the first Global Health EDCTP3 JU projects, many of which have held their kick off meetings and initiated research activities. As of the end of 2023, no project results had been disseminated.

## 2. SUPPORT TO OPERATIONS

## 2.1. Communication activities

In 2023, communication activities of the Global Health EDCTP3 JU focused on four main objectives:

- Establishing new communication channels and tools;
- Promoting funding opportunities;
- Raising awareness about the partnership;
- Promoting funded projects and their results.

These objectives were achieved through the organisation of and participation in events as well as through the development of communication content, activities which have been supported by newly established communication channels.

### Establishing new communication channels and tools

#### Website

A web-presence for the new Joint Undertaking was established in May 2023, when the website was launched. It includes all key information about the Joint Undertaking governance, funding opportunities, news, activities and resources. Funding opportunities are made public through the Funding & Tenders Portal of the European Commission, where participants must submit their proposals, but are also referenced on the Global Health EDCTP3 JU website. The website is regularly updated to ensure all information is correctly showcased.

#### Social media

When announcements have been made and news have been published on the website, such as the publication of the Annual Work Programmes, these have been published on the website, and subsequently promoted on social media.

Social media accounts have been created on X (previously Twitter) and LinkedIn, on 28 March and 15 May 2023 respectively. These platforms are used to share information on the Global Health EDCTP3 JU's activities as well as relevant activities by other stakeholders with the aim to increase visibility of the partnership's activities and ensure continuous engagement with relevant partners.

	Number of posts	Followers gained	Average number of impressions per month
X	424	~1000	20 720
LinkedIn	101	3742	7 089

Top X post published in 2023: Work Programme 2024 publication and funding opportunities [41,000 impressions, 257 likes and 169 reposts to date (March 2024)].

Top LinkedIn post published in 2023: Announcement of the new Global Health EDCTP3 JU Executive Director [6,611 impressions, 160 likes and 18 reposts to date (March 2024)].

### News items

Throughout 2023, seven articles have been published on the Global Health EDCTP3 JU website to announce new activities, funding opportunities or highlight specific actions.

News items and press releases published in 2023:

Title	Date
<a href="#">Global Health EDCTP3 Joint Undertaking: 2023 Work Programme and Info Day</a>	4 April 2023
<a href="#">Open call for expressions of interest for the Stakeholders Group</a>	28 April 2023
<a href="#">Strengthening regulatory capacity in sub-Saharan Africa</a>	30 June 2023
<a href="#">Call for funding opportunities closed: 99 proposals submitted with 392 partners</a>	7 July 2023
<a href="#">Dr Michael Makanga named new Executive Director of the Global Health EDCTP3 Joint Undertaking</a>	3 October 2023
<a href="#">Global Health EDCTP3 Joint Undertaking becomes financially autonomous from the European Commission and begins new implementation phase</a>	24 November 2023
<a href="#">End-of-year message from the Executive Director and publication of the Work Programme 2024</a>	21 December 2023

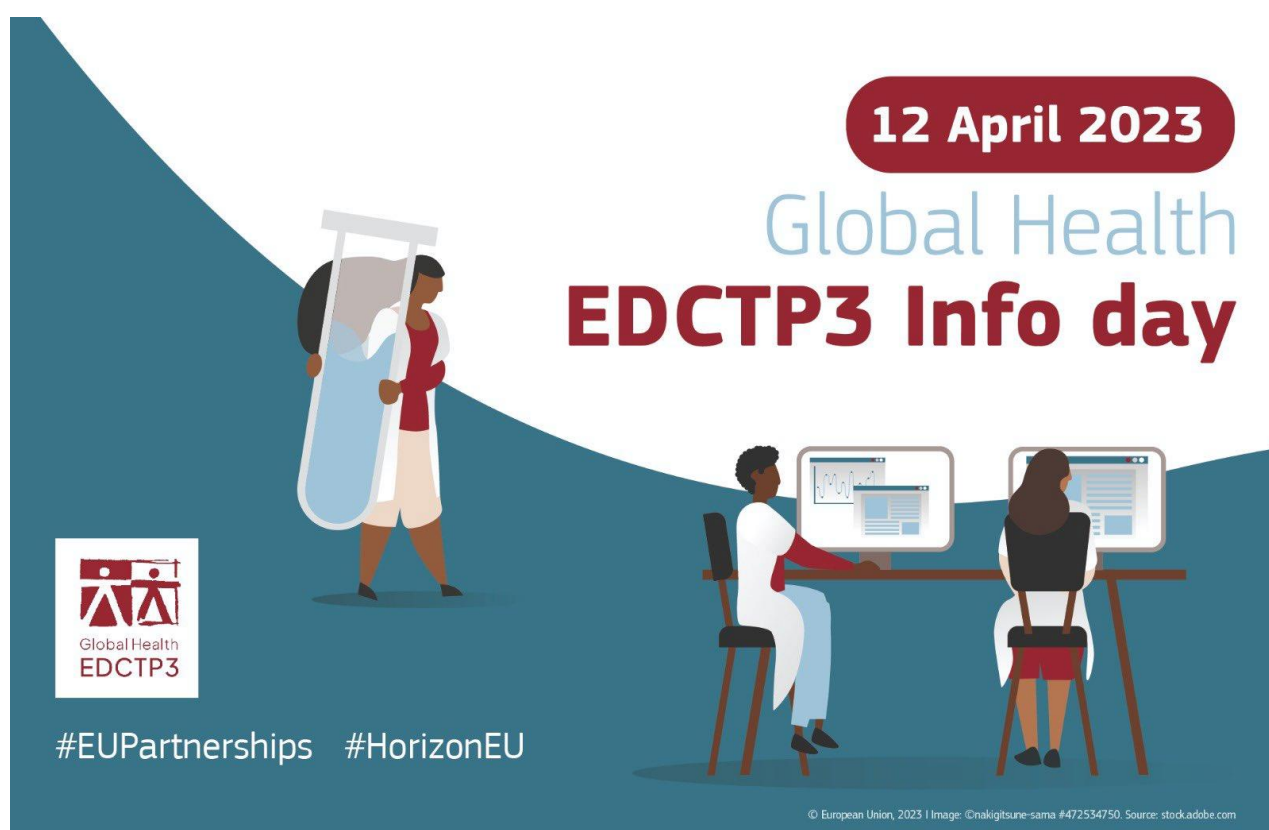
### Promoting funding opportunities

#### Info Days

On 23 March and 12 April 2023, two virtual information session (Info Days) were held to provide potential applicants with information on the Global Health EDCTP3 JU calls for proposals under Work Programme 2023, as well as information on eligibility criteria and other relevant administrative matters. The [Info Day \(Part 1\)](#) held on 23 March aimed to give further guidance to, in particular, research stakeholders based in Africa regarding participation in the Global Health EDCTP3 JU projects and potential membership to the EDCTP Association. The [Info Day \(Part 2\)](#) held on 12 April delved deeper into the different calls for proposals for the year 2023. Both were followed by a question-and-answer session with the online audience.



The event on 23 March was followed live by 278 participants and the one on 12 April counted 287 live participants. Both Info Days were recorded and are hosted on the European Commission's Science and Innovation YouTube channel ([@EUScienceInnovation](#)), allowing all interested parties to refer back to them as well as allowing those who could not participate at the time of the streaming to have access to the information presented. Individually, the recorded videos reached almost 800 views in the months that followed the live events.



#### Other activities to promote the funding opportunities

The publication of the Work Programme 2023 and its corresponding funding opportunities was originally announced on 4 April 2023 on the [European Commission's webpage](#) dedicated to EDCTP3. Once the JU's website was launched, the [corresponding news item](#) was created.

A social media campaign was launched on [X](#) on the same day as the publication of the Work Programme to promote the funding opportunities as well as encouraging potential applicants to participate in the second Info Day (12 April 2023). This campaign was amplified by relevant stakeholders, such as the European Commissioner for Innovation, Research, Culture, Education and Youth, [Mariya Gabriel](#). Once the LinkedIn account became active in May 2023, [posts](#) were also

published to further increase awareness of the funding opportunities among the broadest possible set of potential applicants.

## Raising awareness about the partnership

### EDCTP Forum

The **Eleventh EDCTP Forum** took place on 7-10 November 2023 in Paris under the theme “Partnering for Global Health Research Innovation and Impact in Africa – Celebrating EDCTP: two decades and beyond”. It provided an international platform for the presentation and discussion of cutting-edge research addressing the burden of poverty-related and neglected infectious diseases in sub-Saharan Africa and the capacity development and networking activities that support this goal.

The Forum was hosted by the Ministry of Higher Education and Research of France and ANRS | Emerging Infectious Diseases. The Forum was organised by the EDCTP Association (which implemented the EDCTP2 programme), with support from the Global Health EDCTP3 JU.



Opening ceremony of the EDCT Forum

The Global Health EDCTP3 JU organised several sessions, including:

- Workshop entitled “Presenting the new programme and its opportunities for collaboration”;
- Plenary session entitled “Global Health EDCTP3: strategy and links with other global initiatives”;
- Networking dinner for guests of the Forum.



Global Health EDCTP3 Workshop held on Wednesday 8 November





Plenary session 6 focusing on the aims and goals of Global Health EDCTP3

### External events

Active participation in different global health events is a high priority for the JU Programme Office. Staff attended and/or organised sessions at several key events and meetings, including:

Event	Country	Month
European Molecular Biology Laboratory (EMBL) annual meeting	Germany	May
3rd Africa Health Research and Innovation Funders Forum	South Africa	August
Grand Challenges Forum	Senegal	October
World Health Summit	Germany	October
WHO Global Clinical Trials Forum	Switzerland	November
Global Health Policy Forum	Belgium	November
The International Conference on Public Health in Africa	Zambia	November
Science Forum South Africa	South Africa	December
COP 28	United Arab Emirates	December

The above events allowed the JU Programme Office staff to raise awareness about the new Joint Undertaking, its objectives and its role in supporting research and capacity-building activities to tackle infectious diseases.

Importantly, the Global Health EDCTP3 JU participated in the first ever Health Day at COP 28, including the Reaching the Last Mile Forum side-event, where [we pledged](#) over EUR 46 million to fight Neglected Tropical Diseases (NTDs) in sub-Saharan Africa.

### Prize

In December 2023, Dr Michael Makanga, as newly appointed Executive Director of the Global Health EDCTP3 JU in charge of the Global Health EDCTP3 Programme, was the recipient, on behalf of the EDCTP Programme, of the Prize for Science Diplomacy awarded by the Government of South Africa during the Science Forum South Africa for its contribution to tackling infectious diseases and fostering research excellence. Moreover, at this high-level Forum we hosted a session on the role of health research in achieving sustainable development.

### **Promoting funded projects and their results**

Projects funded under the Global Health EDCTP3 JU have started in the course of 2023 and as such, tangible results and outcomes included could have led to specific communication activities have not yet been achieved.

In 2023, communication activities regarding projects have been focused on grants signature, kick-off meetings and activities that the projects have carried out. A [news item](#) was published on 30 June highlighting the six projects funded under the Work Programme 2022 working on strengthening regulatory capacity in sub-Saharan Africa.

Another example of communication activities related to signed projects includes amplifying the project's own actions on social media.

## **2.2. Legal and financial framework**

The Global Health EDCTP3 Joint Undertaking operates under the framework of its founding regulation, Council Regulation (EU) 2021/2085<sup>6</sup>:

In addition to it, the following rules have been adopted in 2022 and 2023:

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<sup>6</sup> Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014.

### Governing Board decisions

- Decision adopting the Financial Rules of the Global Health EDCTP3 JU of 3 May 2022 – GH-EDCTP3-GB/22/2022;
- Decision adopting the Internal Control Framework of 3 August 2023 – GH-EDCTP3-GB/11/2023;
- Decision on adopting the internal audit capability of 28 September 2023 – GH-EDCTP3-GB/25/2023;
- Decision approving the date on which the Global Health EDCTP3 Joint Undertaking will have the capacity to implement its own budget – Financial autonomy of 7 November 2023 – GH-EDCTP3-GB/31/2023.

### Executive Director decisions

- Decision GH-EDCTP3-ED/21/2023 on the adoption of the Global Health EDCTP3 JU manual of financial procedures;
- Decision of the Executive Director GH-EDCTP3-ED/22/2023 on the adoption of the action plan on the internal control framework of the Global Health EDCTP3 JU.

## 2.3. Budgetary and financial management

The annual budget for year 2023 was adopted by the Governing Board on 3 April 2023, per Decision GH-EDCTP3-GB/05/2023 “Annual Work Programme 2023 and Annex I (call topics) and Annex II (IKAAs)”.

There were two amendments of the budget during 2023:

### Amendment number 1 – Before financial autonomy

The Annual Budget for year 2023 was amended for the first time on 21 November 2023 (before the financial autonomy of the JU on 23 November 2023), per Decision GH-EDCTP3-GB/32/2023.

Following the preparation for the Global Health EDCTP3 JU’s financial autonomy in the accounting system (ABAC), the Executive Director proposed an adaptation of the budget in the Statement of Expenditure to the Governing Board: a transfer of EUR 2 923 466 of both commitment and payment appropriations from administrative expenditure (Title 1 and 2) to operational expenditure (Title 3). This transfer was proposed since the administrative expenditure was lower than budgeted and the unused appropriations would allow the JU to fund additional proposals from the reserve list, as the response to the calls was high and the success rate low.

Consequently, Title 1 was amended to EUR 1 831 800 and Title 2 to EUR 904 734 bringing the total administrative expenditure to EUR 2 736 534. The operational expenditure (Title 3) was amended to EUR 134 820 778.

In addition, an amount of EUR 190 000 was transferred from budget line “Meeting expenses” (Title 2) to “External services” (Title 1) in order to ensure sufficient appropriations in the destination budget line for commitments level 2 position.

### Amendment number 2 – After financial autonomy

The Executive Director proposed an adaptation of the budget due to technical and administrative issues with the transfer of files from the European Commission to the Global Health EDCTP3 JU in the accounting system (ABAC) linked to the process of financial autonomy. Therefore, the amount of payment appropriations for operational expenditure in the Annual Budget for year 2023 needed to be decreased by EUR 4 790 048.

This transfer was reflected in both the Statement of Revenue and the Statement of Expenditure.

The last amendment was approved by the Governing Board on 18 December 2023, per Decision GH-EDCTP3-GB/43/2023.

### Credit operations between budget lines under Title 2

In December 2023, credit operations as per the Global Health EDCTP3 JU Financial Rules Article 12(2) were approved by the Executive Director, per Decision GH-EDCTP3-ED/29/2023.

The transfers of appropriations for both commitments and payments referred to the following budget lines and amounts under Title 2 “Infrastructure and operating expenditure”:

- EUR 140 000 from budget line “220 – *Office equipment (movable property and associated costs)*” (total amount after amendment EUR 21 142) to budget line “210 – *Information, communication technology and data processing*” (total amount after amendment EUR 294 537);
- EUR 50 000 from budget line “270 – *Information and publishing*” (total amount after amendment EUR 149 144) to budget line “280 – *Service contracts*” (total amount after amendment EUR 86 018).

The total amount for administrative expenditure (Title 2) remained unchanged. At the end of year 2023, the JU executed 100% of its commitment appropriations available in active budget (Titles 1 to 3). Concerning the payment appropriations, a rate of 47% was implemented.



## Statement of revenue

Statement of revenue:	Initial voted budget (AWP) - 2023		Second amendment of the budget after the financial autonomy on 23 November 2023	
Heading	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	Commitment appropriations (in EUR)	Payment appropriations (in EUR)
EU contribution excl. EFTA	1 33 693 568,00	54 441 083,00	1 33 693 568,00	49 651 034,00
of which Administrative	5 523 568,00	5 523 568,00	2 600 102,00	2 600 102,00
of which Operational	128 170 000,00	48 917 515,00	131 093 466,00	47 050 932,00
EFTA and third countries contribution	3 863 744,00	1 573 347,00	3 863 744,00	1 573 348,00
of which Administrative	159 631,00	159 631,00	136 432,00	136 432,00
of which Administrative third countries excluding EFTA	3 704 113,00	1 413 716,00	3 727 312,00	1 436 916,00
of which Operational	-	-	-	-
Industry financial contribution	-	-	-	-
of which Administrative	-	-	-	-
of which Operational	-	-	-	-
Other revenue	-	-	-	-
SUB-TOTAL REVENUES	1 37 557 312,00	56 014 430,00	1 37 557 312,00	51 224 382,00
Reactivation of unused appropriations from administrative expenditure				
Of which from YEAR N-31	N.A.	N.A.	N.A.	N.A.
Of which from YEAR N-21	N.A.	N.A.	N.A.	N.A.
Of which from YEAR N-11	N.A.	N.A.	N.A.	N.A.
Reactivation of unused appropriations from operational expenditure				
Of which from YEAR N-31	N.A.	N.A.	N.A.	N.A.
Of which from YEAR N-21	N.A.	N.A.	N.A.	N.A.
Of which from YEAR N-11	N.A.	N.A.	N.A.	N.A.
TOTAL	1 37 557 312,00	56 014 430,00	1 37 557 312,00	51 224 382,00

## Statement of expenditure – Commitment appropriations

Statement of Expenditure	Initial voted budget – 2023 (AWP) (in EUR)	Transfers made in the first and second amendment of the budget (in EUR)	Final amended budget after the financial autonomy on 23 November 2023 (in EUR)	Available budget after the financial autonomy on 23 November 2023 (in EUR)*	Executed Budget – 2023 (in EUR)	%	Available for future use (N+3 rule) (in EUR)
Commitment appropriations							
Title 1 – Staff expenditure	3 519 369	-1 687 569	1 831 800	758 646	541 614	71%	217 032
Salaries & allowances	3 202 522	-1 877 569	1 324 953	323 621	265 112	82%	58 509
Expenditure relating to Staff recruitment	1 32 920	0	1 32 920	1 31 195	29 100	22%	1 02 095
Mission expenses	71 723	0	71 723	37 292	37 292	100%	0
Socio-medical infrastructure	33 230	0	33 230	33 137	21 441	65%	11 696
Training	53 498	0	53 498	52 478	11 280	21%	41 198
External services	22 153	190 000	212 153	177 600	176 399	99%	1 201
Receptions, events and representation	3 323	0	3 323	3 323	990	30%	2 333
Title 2 – Infrastructure and operating expenditure	2 140 631	-1 235 897	904 734	864 581	585 904	68%	278 676
Rental of buildings and associated costs	220 000	0	220 000	220 000	157 988	72%	62 012
Information, communication technology and data processing	531 248	-236 711	294 537	263 939	240 954	91%	22 984
Office equipment (movable property and associated costs)	1 61 142	-1 40 000	21 142	17 756	1 156	7%	16 600
Current administrative expenditure	92 094	0	92 094	92 094	0	0%	92 094
Postage / Telecommunications	40 314	0	40 314	40 314	427	1%	39 887
Meeting expenses	407 485	-406 000	1 485	1 076	0	0%	1 076
Running costs in connection with operational activities	1 39 204	-1 39 204	0	0	0	0%	0
Information and publishing	1 99 144	-50 000	1 49 144	1 49 144	1 41 059	95%	8 085
Service contracts	350 000	-263 982	86 018	80 258	44 320	55%	35 938
Title 3 – Operational expenditure	1 31 897 312	2 923 466	1 34 820 778	1 34 820 778	1 34 721 055	100%	99 723
Current year's Calls/other funded actions							N.A.
TOTAL	1 37 557 312	0	1 37 557 312	1 36 444 005	1 35 848 573	100%	595 431

\* Available budget after financial autonomy on 23 November 2023 (in EUR): These amounts represent the available budget in commitment appropriations that the JU had available in its accounting system (ABAC) after financial autonomy, taking into account the consumption of the budget that took place when the JU was running under the European Commission (DG RTD) before financial autonomy, i.e., from 1 January 2023 to 22 November 2023.

## Statement of expenditure – Payment appropriations

Statement of Expenditure	Initial voted budget – 2023 (AWP) (in EUR)	Transfers made in the first and second amendment of the budget (in EUR)	Final amended budget after the financial autonomy on 23 November 2023 (in EUR)	Available budget after the financial autonomy on 23 November 2023 (in EUR)*	Executed Budget – 2023 (in EUR)	%	Available for future use (N+3 rule) (in EUR)
Payment appropriations							
Title 1 – Staff expenditure	3 519 369	-1 687 569	1 831 800	751 243	183 370	24%	567 873
Salaries & allowances	3 202 522	-1 877 569	1 324 953	323 621	160 883	50%	162 738
Expenditure relating to Staff recruitment	1 32 920	0	1 32 920	1 31 195	2 400	2%	1 28 795
Mission expenses	71 723	0	71 723	36 999	3 563	10%	33 436
Socio-medical infrastructure	33 230	0	33 230	33 111	2 360	7%	30 751
Training	53 498	0	53 498	52 478	0	0%	52 478
External services	22 153	190 000	212 153	170 515	14 164	8%	156 351
Receptions, events and representation	3 323	0	3 323	3 323	0	0%	3 323
Title 2 – Infrastructure and operating expenditure	2 140 631	-1 235 897	904 734	803 110	317 900	40%	485 210
Rental of buildings and associated costs	220 000	0	220 000	220 000	152 754	69%	67 246
Information, communication technology and data processing	531 248	-236 711	294 537	21 413	155 145	72%	58 986
Office equipment (movable property and associated costs)	1 61 142	-1 40 000	21 142	17 756	0	0%	17 756
Current administrative expenditure	92 094	0	92 094	92 094	0	0%	92 094
Postage / Telecommunications	40 314	0	40 314	40 314	0	0%	40 314
Meeting expenses	407 485	-406 000	1 485	512	0	0%	512
Running costs in connection with operational activities	1 39 204	-1 39 204	0	0	0	0%	0
Information and publishing	1 99 144	-50 000	1 49 144	1 49 144	0	0%	1 49 144
Service contracts	350 000	-263 982	86 018	69 158	10 000	14%	59 158
Title 3 – Operational expenditure	50 354 430	-1 866 582	48 487 848	624 221	518 522	83%	1 05 699
Current year's Calls/other funded actions							N.A.
TOTAL	56 014 430	-4 790 048	51 224 382	2 178 573	1 019 792	47%	1 158 781

\* Available budget after financial autonomy on 23 November 2023 (in EUR): These amounts represent the available budget in payment appropriations that the JU had available in its accounting system (ABAC) after financial autonomy, taking into account the consumption of the budget that took place when the JU was running under the European Commission (DG RTD) before financial autonomy, i.e., from 1 January 2023 to 22 November 2023.

### **Administrative costs: Title 1 (Staff Expenditure) and Title 2 (Infrastructure and Operating Expenditure)**

Title 1 and Title 2 of the budget were executed up to 71% and 68% respectively in commitment appropriations.

Title 1 (Staff Expenditure) was mainly used for the salaries of the JU staff and recruitment costs.

On top of that, a significant amount of this execution rate was used in the contribution agreement related to schools and childcare facilities.

In addition, related commitments were made in the field of missions of the staff during the year and different Service Level Agreements (SLAs) signed with the European Commission (mostly with DG HR) among others.

Title 2 (Infrastructure and Operating Expenditure) was mostly used for the rental costs of the White Atrium offices and the purchase of different IT equipment for the setting up of the JU.

The several events in Paris around the EDCTP Forum held from 7 to 10 November 2023 also represented a significant amount together with the signature of the SLA with the DG Budget and other JUs.

The implementation rate of the payment appropriations was 24% for Title 1 and 40% for Title 2.

Concerning Title 1, these payments comprise mainly staff salaries, mission expenses and external services such as the monthly interim staff contract with Randstad and school transportation.

As per Title 2, payments were made to honour the rental of the offices and invoices covering costs for different IT supplies among others.

In this regard, it is important to highlight that the financial autonomy of the Global Health EDCTP3 JU was achieved on 23 November 2023. After autonomy, the JU received cash for the first time from the Commission in its bank account (first instalment of the EU contribution 2023) on 14 December 2023, a week before the last working week of the year. Despite the very limited available time, all outstanding invoices and debit notes were paid on time in 2023.

### **Operational costs: Title 3**

Title 3 constitutes the JU's operational budget for the implementation of the Global Health EDCTP3 JU programme activities under Horizon Europe, achieving an execution rate in commitment appropriations of 100%.

The majority of the JU's budget under this category is represented by the two calls for proposals launched in 2023: the single-stage call (EUR 78 223 466) and the two-stage call (EUR 56 000 000).

The cost for expert evaluators, a service which is managed by REA, is also included under Title 3.

The implementation rate of the operational budget in payment appropriations was 83%.

In 2023, most of the payment appropriations were used for the pre-financing of the grants resulting from the 2022 calls for proposal (EUR 47 812 540), for the expert costs (EUR 476 685) and for the payments to the members of the Scientific Committee (around EUR 88 610).

## 2.4. Financial and in-kind contributions from Members other than the Union and Impact of the contributions

### 2.4.1. Financial and in-kind contributions

The Global Health EDCTP3 Joint Undertaking is funded by its members and contributing partners. The legal regime regarding contributions from members other than the Union and related conditions is based on the Founding Regulation, in particular Articles 2(8 to 10), 11, 103 and 104.

The member other than the Union, the EDCTP Association, will arrange for its constituent or affiliated entities to make a total contribution of at least EUR 439 878 000, which can consist of IKAA, IKOP and/or financial contribution.

The expected contribution from the EDCTP Association is predominantly in the form of IKAA. For the year 2023, the EDCTP Association submitted a plan, which was approved by the Governing Board, to initiate, through its constituents, additional activities with an estimated value of EUR 86 621 213. This brings the total estimated value of all initiated additional activities by the end of year 2023 to EUR 387 605 543. It should be noted that these additional activities are largely multi-annual in duration.

In year 2023, the JU has received a report from the EDCTP Association by 31 May 2024 that for the additional activities initiated in previous years, years 2022 and 2023, EUR 152 821 896,00 have been incurred. Out of this amount, none has been certified yet. Due to the multi-annual duration of most of the additional activities, it has been agreed that the certification may or may not take place or be submitted annually but the 'cumulative' certified amount should cover the entire value reported. It is the certified value that will be validated by the Governing Board as IKAA.

It is to be noted that the EDCTP Members planned value to be initiated in year 2023 in accordance with the Work Programme 2023 and associated validated IKAA plan as well as in the previous years is estimated for a total of **EUR 387 605 543,00**. The JU, together with the EDCTP Association is currently preparing a guidance document for the certification of Member's reported contribution, and in

collaboration with Members States. It is expected that by 31 May 2025, the JU would be able to report certified Members contribution for the year 2022, 2023 and 2024, and for a total value between EUR 388 million (total estimated) and EUR 153 million (currently reported for 2022 and 2023).

Finally, EUR 15 565 115,04 contribution from Contributing Partner is now reported as estimated Financial Contribution, from Bill & Melinda Gates Foundation, confirmed in the signed project NGS4PublicHealth. The value is based on the total project costs less the total EU contribution to the project. The project was started in September 2022 and is expected to be finalized in January 2026.

Contributions from JU Members other than the Union cumulatively reported by the end of 2023	
Nature	Amount (in EUR)
Financial contributions (FC) reported	15 565 115,04
In-Kind to Operational Activities (IKOP) reported	N/A
In-Kind to Additional Activities (IKAA) reported	152 821 896
In-Kind to Additional Activities (IKAA) reported and certified	0
<b>TOTAL all contributions reported</b>	<b>168 387 011,04</b>
<b>TOTAL all contributions reported, including certified IKAA</b>	<b>168 387 011,04</b>

The mandatory annual IKAA report to be added in Annex 9 of this CAAR is based on the reported p Additional Activities Plan (AAP) presented by the private members and planned at programme level (in annex to the annual work programme or following GB decisions) or at project level (following results of calls and consequent GB decisions) that have been pre-approved by the JU GB (except in exceptional circumstances). Those IKAA incurred during the preceding years should be reported by the members by 31 May each year in line with the requirements of Article 11(2) of the SBA.

## 2.4.2. IKAA Impact contribution to the Global Health EDCTP3 JU

Among the activities already reported, reference can already be made to the following IKAA leveraging major impact on the EDCTP3 Programme:

### Malaria

The Multi-Stage Malaria Vaccine Consortium, MMVC (IKAA-EDCTP3-2023-3450) progressed the clinical development of the R21/Matrix-M™ which has culminated in the 2023 WHO recommendation for the use of new malaria vaccine R21/Matrix-M, for the prevention of malaria in children. This highly effective vaccine was developed by the Jenner Institute at Oxford University and Serum Institute of India with support from EDCTP, the Wellcome Trust, and the European Investment Bank. The R21 vaccine is the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine, which received a WHO recommendation in 2021. The addition of R21 to the list of WHO-recommended malaria vaccines is expected to result in sufficient vaccine supply to benefit all children living in areas where malaria is a public health risk. The R21/Matrix-M malaria vaccine is an easily deployable vaccine that can be manufactured at mass scale and modest cost, enabling as many as hundreds of millions of doses to be supplied to countries which are suffering a significant malaria burden. To date the R21/Matrix-MTM malaria vaccine has been licensed for use in Ghana, Nigeria and Burkina Faso. In combination with public health measures, such as the use of insecticide-treated bed nets and seasonal malaria chemoprevention, this vaccine can help save and improve the lives of millions of children and their families.



Field activities at the Nanoro vaccine trial site, Burkina Faso (Multi-Stage Malaria Vaccine Consortium, MMVC)





*Infant being administered malaria vaccine, Nanoro, Burkina Faso (Multi-Stage Malaria Vaccine Consortium, MMVC)*

In malaria treatment the WANECAM-II study ([IKAA-EDCTP3-2024-3520](#)) is advancing the clinical development and registration of KAF156 combined with lumefantrine (in a Solid Dispersion Formulation, LUM-SDF). KAF156, an imidazolepiperazine compound, is one of the leading candidates in the antimalarial drug development pipeline. It is a novel antimalarial drug being developed by Novartis with scientific and financial support from EDCTP and MMV (in collaboration with the Bill & Melinda Gates Foundation). The product development plan includes two consecutive steps with the ultimate objective to seek whether KAF156 + LUM-SDF is non-inferior to Artemether-Lumefantrine (AL, registered named Coartem®) in safety and efficacy for the treatment of uncomplicated falciparum malaria. The first step (KALUMI study, [NCT04546633](#); single-arm phase II study in 3 age-descending cohorts) will assess the pharmacokinetics, safety and efficacy of KAF156 + LUM-SDF in infants, including young children aged 6 months to 12 years, based on the knowledge gained about the safety and efficacy of KAF156 + LUM-SDF in older age children. The second step (KALUMA study) will be a phase III trial to assess safety and efficacy of KAF156 + LUM-SDF in the treatment of uncomplicated falciparum malaria in children and adults. Due to the delays caused by COVID-19 KALUMI trial is ongoing while KALUMA trial is in preparation. Continuation of these clinical trials has been made possible through EDCTP-Association member states funding, part of the Global Health EDCTP3 JU.



## HIV

The PrEPVacc HIV prevention study (IKAA-EDCTP3-2023-3447) announced at the International Conference on AIDS and Sexually Transmitted Infections (STIs) in Africa (ICASA 2023) that it stopped development of its experimental vaccine. PrEPVacc's leadership decided to stop immediately vaccination of individuals in the trial based on the recommendation of its independent data monitoring committee (IDMC), which also recommended that the oral PrEP component of the study continue to completion. The stopping of further vaccinations in PrEPVacc underlines how challenging it is to develop an effective HIV vaccine. To date, only the RV144 'Thai trial' showed some efficacy in reducing HIV acquisition by 31.5% at three years. However, the PrEPVacc trial has been commended by the scientific community for its excellent trial management as well as commitment of trial participants and communities, without whom scientific gains into HIV prevention would not be possible. While the vaccine did not produce immunity to HIV, the trial has succeeded in building the capacity to conduct large, complex efficacy trials in East and Southern Africa. Furthermore, PrEPVacc will also provide key data on optimised forms of PrEP. This is valuable for informing future implementation and uptake strategies by local stakeholders in settings where PrEP uptake is low, even when accessible.

Among adolescents and adults who are co-infected with HIV and TB, DATURA (IKAA-EDCTP3-2024-3520) is evaluating whether an intensified initial TB treatment could increase survival in this severely immunocompromised group. The project has potential to contribute to future national and international guidelines for the management of TB in HIV-infected patients. 1330 HIV-infected adults and adolescents with low CD4 cells count (<100 cells/μL), hospitalised for TB, are participating in a randomised clinical trial in 4 African countries. The trial is currently ongoing and the results are expected in 2025.

Core funding provided by Germany to the product development partnership International Partnership for Microbicides (IPM) (IKAA-EDCTP3-2022-3376) has contributed towards continued regulatory submissions for the Dapivirine Vaginal Ring (DapiRing™), a long-acting, user-controlled vaginal ring developed by IPM to reduce the risk of HIV transmission during vaginal sex. The DapiRing received a positive scientific opinion in July 2020 from the European Medicines Agency (EMA) for use among women ages 18 and older. The ring has received regulatory approval in several African countries with additional applications pending and planned for 2023. The ring has also received Prequalification and a recommendation from WHO. The additional funding provided in 2022/2023 builds on earlier investments made by Germany, Ireland, the Netherlands, the UK and others through PDP funding supported as EDCTP2 Participating States Initiated Activities (PSIAs) and will support continued regulatory submissions in eastern and southern Africa, where the need for new prevention methods is urgent, preparations for the ring's introduction where it is approved, and R&D for a follow-on DVR that could be used for three months at a time.

## Tuberculosis

In TB diagnostics **TB TRIAGE+** (IKAA-EDCTP3-2024-3520) is assessing the accuracy, impact and cost-effectiveness of CAD4TB and C-reactive protein as triage tools for community-based TB screening in rural and semi-rural Lesotho and KwaZulu-Natal, South Africa. WHO has developed target product profiles for community-based TB triage testing. CAD4TB, an extensively validated digital chest x-ray analysis platform using deep-learning technology, and a blood test for C-reactive protein, which is a marker of inflammation or infection, are two very promising diagnostic tools which have the potential to meet the targets for TB triage. The studies are expected to complete in the third quarter of 2024. The development of an accurate, robust and cost-effective TB community-based triage algorithm will improve access to quality health care for hard-to-reach populations.

Likewise, in TB diagnostics the aim of PreFIT (IKAA-EDCTP3-2024-3520) is to contribute to the development of new tools to predict the progression of latent tuberculosis to active disease. Diagnostic technologies to accurately detect who will develop active TB are under development. However, their performance in high burden settings is largely undescribed. PreFIT aims to validate assays for improved prediction of progression from latent tuberculosis infection (LTBI) to active tuberculosis (TB) disease. Assays with high positive predictive value (PPV) for progression to TB disease have great potential for reducing TB morbidity and mortality in Africa by allowing scale-up of preventive treatment, which is becoming possible with shorter, safer preventive treatment regimens. The study is ongoing and is estimated to complete in the third quarter of 2024.

Core funding provided by Germany to the product development partnership the Global Alliance for TB Drug Development (TB Alliance) (IKAA-EDCTP3-2022-3376) is enabling TB Alliance to continue to pursue necessary further breakthroughs in TB therapy – shorter regimens of safer and more effective drugs – to accelerate the reduction of the TB disease burden, and ultimately achieve its elimination. Specifically, TB Alliance will continue rolling out the breakthrough BPaL regimen consisting of the oral drugs bedaquiline, pretomanid and linezolid, striving for updated global guidance and additional regulatory approvals for the regimen to be used in highly drug-resistant TB patients. The BPaL regimen is a six to nine months regimen that replaces the previously recommended 18 to 24 months treatment, including an injectable agent, for patients with highly resistant TB. Since BPaL is an all-oral treatment, patients no longer have to undergo painful daily injections for months. But most of all, the new regimen offers a much greater chance of a cure. The latest data reported to WHO showed a dismal global success rate of 39% amongst patients with extensively resistant TB; the BPaL regimen had a 90% favourable response in patients treated in a clinical trial setting. The BPaL regimen has been approved by the US Food and Drug Administration and the European Commission, and recently recommended by the World Health Organization under operational research conditions. Concurrently, TB Alliance is developing a universal regimen that is effective against all forms of TB, by researching safer oxazolidinones and diarylquinolines. The additional funding provided in 2022/2023 builds on earlier investments made by Germany, Ireland, the Netherlands, the UK and others through PDP funding supported as EDCTP2 Participating States Initiated Activities (PSIAs).

## Neglected infectious diseases

In December 2023, the CHMP of EMA adopted a [positive scientific opinion of the use of Fexinidazole Winthrop](#) as first oral treatment for *T.b. rhodesiense* sleeping sickness. The trial for treatment with Fexinidazole Winthrop in Malawi and Uganda was supported by EDCTP through the [HAT-r-ACC consortium](#) with co-financing from Germany, the Netherlands and the UK through the product development partnership, Drugs for Neglected Diseases initiative (DNDi) (IKAA-EDCTP3-2022-3372, IKAA-EDCTP3-2022-3376 and IKAA-EDCTP3-2024-3516). Fexinidazole Winthrop is indicated as a 10-day once-a-day oral treatment for *T.b. rhodesiense*. The treatment has already been registered in the Democratic Republic of Congo (DRC) and Uganda as a treatment for *T.b. gambiense* and is recommended for use in a further 10 African countries (Angola, Burkina Faso, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, and South Sudan). The CHMP opinion paves the way for the update of World Health Organization (WHO) guidelines on sleeping sickness, as well as the extended indication and distribution of fexinidazole in African countries where *T.b. rhodesiense* is prevalent.

## Diarrheal diseases

EDCTP is supporting evaluation of Etvax® in phase I studies in adults and progressively younger children in Zambia, followed by a phase IIb study in infants in The Gambia and a phase III in Zambia in children 6–40 months of age (IKAA-EDCTP3-2023-3448). Data from these trials will be critical for seeking licensure and WHO prequalification. ETVAX is currently the most advanced enterotoxigenic *Escherichia coli* (ETEC) candidate vaccine in clinical development.

## Lower respiratory tract infections

Among HIV positive children with respiratory infections, EMPIRICAL trial (IKAA-EDCTP3-2024-3520)

is evaluating whether empirical treatment against TB and *cytomegalovirus* improves survival of HIV-infected infants with severe pneumonia. The mortality rate in this population is very high and more than one-quarter of those admitted with pneumonia die during admission while another 25% died in the first months after discharge. HIV-infected infants aged between one month and 12 months are receiving the usual pneumonia treatment of antibiotics, cotrimoxazole and prednisolone. Those thought to have a TB infection will receive anti-TB treatment, and half will also be given an antiviral, valganciclovir. Those not thought to have TB will randomly receive either valganciclovir or anti-TB treatment, on top of the usual pneumonia treatment. Survival will be compared at 15 days and after a year. The trial is ongoing with no major safety concerns reported and the results are expected in 2025.

## Emerging and re(emerging) diseases

EDCTP2-funded epidemic preparedness networks – ALERRT and PANDORA-ID-NET – have made coordinated efforts to enhance countries' abilities to manage the COVID-19 pandemic, as well as

raising awareness of its impact on other infectious diseases. Part of this work has been carried out in partnership with EDCTP Regional Networks (**IKAA-EDCTP3-2023-3449** and **IKAA-EDCTP3-2024-3520**).

**ALERRT** revised the protocol of its **FISSA study** (Febrile Illness in Sub-Saharan Africa) to include a research response component in the event of a declaration of a Public Health Emergency by national or international health authorities in the countries participating in the FISSA study. FISSA is an observational study taking place in 16 healthcare centres in sub-Saharan Africa which recruited over 8,000 participants, including children aged 2 years and above. The consortium has shared summary results at their annual meeting in May 2023, but have not yet presented to external stakeholders. With complementary funding from the Wellcome Trust and the UK Foreign, Commonwealth and Development Office (£1.4 million) working closely with the WHO-AFRO, Africa CDC and existing networks such as ISARIC and structures across Africa, ALERRT set up **the COVID-19 clinical characterisation protocol (CCP)**, a study nested within the FISSA study. Almost 7,000 patients have been enrolled in the CCP ‘nested’ study.

The emergence of the SARS-CoV-2 infection and pandemic provided a unique opportunity for the **PANDORA-ID NET** consortium to undertake ad hoc studies in support of the African response to this disease. These included elements of risk analysis on introduction of the virus by air transport routes; evaluation of the zoonotic aspects and their relevance to the COVID-19 pandemic; impacts of lockdown as a measure in African countries on the virus and communities. To date PANDORA-ID-NET project as well as members of the PANDORA consortium have published around 200 articles on COVID-19 (a full list is available on the project’s **website**). Despite emergence of new COVID-19 research priorities, PANDORA continued implementing studies on other diseases: a study in Uganda on surveillance of Crimean Congo Haemorrhagic fever (CCHF) prevalence and studies on LASSA fever in Sierra Leone. The consortium also completed studies in Tanzania to determine the seroprevalence of chikungunya, dengue and Zika in diverse ecological zones. PANDORA ID NET played a critical supportive role in the drafting, consultation and final publishing of the **Africa CDC framework for One Health practice** in national public health institutions. This is a guiding document supporting One Health implementation that the Africa CDC is utilising to advise and support African Member States. Furthermore, the consortium contributed to a global One Health stakeholder analysis which resulted in publication by the Lancet a four-paper series in January 2023, examining critical issues of a One Health approach. This four-paper **Lancet Series** explores the adoption of One Health approaches to improve health security and include an analysis of the current landscape of preventive, surveillance, and response measures in outbreak situations of emerging and re-emerging zoonotic infectious diseases with epidemic potential as well as other potential public health emergencies such as neglected endemic diseases, antimicrobial resistance, environmental and chemical hazards and natural disasters.





*Dr Francine Ntoumi and the team of the PANDORA-ID-Net project*



*Scientists at work in the context of the PANDORA-ID-Net project*

## EDCTP Regional Networks

The EDCTP2 programme supports four Regional Networks of Excellence in Central, East, Southern and Western Africa (CANTAM, EACCR, TESA and WANETAM), to promote regional networking and provide platforms for research training and multicentre studies. Each of the networks comprises multiple institutions in sub-Saharan African countries, as well as European partners, and conduct activities to develop capacity in countries that do not have a strong tradition of clinical research. The establishment of networks provided an opportunity for infrastructural upgrades to achieve compliance with international requirements. Seven laboratories in the networks have achieved and/or maintained their ISO 15189:2012 accreditation (medical laboratories requirements for quality and competence). These accredited laboratories based in The Gambia, Kenya, Mozambique, Nigeria, Senegal, Tanzania and Uganda, are now able to compete globally for high-quality research projects adhering to highest international standards and are helping to raise quality standards at other labs in the networks. The networks are also helping to advance representation of women in science. Under the EDCTP umbrella, the UK has funded an initiative enabling 32 female researchers to progress through PhD programmes coordinated by EDCTP Regional Networks of Excellence (**PSIA2020AGDG**), which will receive supplementary funding in 2024 to support additional female researchers (**IKAA-EDCTP3-2024-3520**).

The importance of the EDCTP Regional Networks of Excellence as a platform for conducting research in Africa, including for epidemic preparedness and response, has become increasingly recognised during the COVID-19 pandemic. The EDCTP strategy in launching the [call for the epidemic-preparedness networks](#) was to ensure synergy with existing research networks, build upon existing capacity at the Networks of Excellence, maximising the utilisation and impact of the clinical trials research capacity developed across Africa by the Networks. There is cross-membership between CANTAM, EACCR, WANETAM networks and ALERRT and PANDORA-ID-NET, as well as active collaborations on specific activities.

[The Central African Network on TB, HIV and Malaria \(CANTAM\)](#): Addressing gender gaps in clinical research capacity is one of the priority areas for CANTAM, which led it to develop a strategy to involve more women in medical research. The network initiated a project entitled ‘Women and Science’ targeted at local schools and aims to mitigate the marginalisation of female scientists through the establishment of a career development fellowship for post-doctoral female researchers. This project is being rolled out across Central Africa via the EDCTP2-funded fellowship programme [WISE \(PSIA2020AGDG-3316\)](#) which aims to strengthen gender capacity in clinical research within the CANTAM network. During its second phase, CANTAM has successfully completed the Pyronaridine-artesunate antimalarial (PYRAMAX) clinical trial funded by Medicines for Malaria Venture (MMV), hence contributing to the new WHO guidelines on malaria (2022).

[The East African Consortium for Clinical Research \(EACCR\)](#) invests in preparing resource-limited clinical research sites to conduct clinical trials on the infectious diseases that burden the region. EACCR has developed an e-learning centre that hosts peer-reviewed short courses required for high-quality clinical studies. Through its reciprocal monitoring scheme, the network established a regional

pool of 25 trained clinical trial monitors. The monitors are qualified to be independent monitors, four of whom also received accreditation with the Association of Clinical Research Professionals. Under EACCR a total of 22 sister sites had their infrastructure upgraded. This included three laboratories that received ISO certification. Following these upgrades, some sites have participated in clinical study activities. For example, the Uganda Virus Research Institute (UVRI) clinic, which received a data management office setup and a participant sitting area, is now participating in the Fevers in Sub Saharan Africa (FISSA) study led by the ALERRT consortium. The Mawenzi site in Tanzania is now involved in three clinical trials. The network carried out more than six short studies over a period of four years.

The [Trials of Excellence in Southern Africa \(TESA\)](#) network established specific reference laboratories on HIV (Botswana–Harvard AIDS Institute Partnership), TB (Stellenbosch University) and malaria (Manhiça Health Research Centre). The laboratories serve as a training platform to optimise the use of resources among the members. Building on the capacity developed through TESA, the site in Zambia is leading a national study on “COVID-19 Patient Characterization in Zambia”. The sub-investigators who received GCP/GCLP and data management training under TESA are now actively involved in clinical research. For example, Dr Mwansa Ketty Lubeya has developed a sub study protocol on COVID-19 in pregnancy and served as member of the editorial committee on the [Clinical Guidance for Management of Patients with COVID-19](#) by the Zambian Ministry of Health. Scientists from the TESA NoE based at the [Botswana Harvard AIDS Institute Partnership were recognised in 2023](#) during a visit by Dr Tedroshebreyesus, Director-General of WHO for their part in the discovery of the Omicron variant.

The [West African Network for Tuberculosis, AIDS and Malaria \(WANETAM\)](#) has been collaborating with Africa Centres for Disease Control and the West Africa Health Organization (WAHO). WAHO and WANETAM have established a framework supporting laboratories in the region to achieve accreditation, with the Centre for Tuberculosis Research at the Nigeria Institute of Medical Research being the first laboratory supported under this collaboration to receive international ISO15189:2012 accreditation. WANETAM has also set up a controlled human infection model in The Gambia, the first of its kind of West Africa. In addition, the TB in children–team of WANETAM established a sub-network, the West African Paediatric TB Network (WApTBNet).

## 2.5. Administrative Procurement and contracts

The Global Health EDCTP3 JU is party to several framework contracts concluded by the Commission or other EU organisations as a participating contracting authority. This includes framework contracts accessible through the procurement back-office arrangement, led by Clean Aviation JU.

Subject of the contract	Type of Contract <sup>III</sup>	Contractor	Tender Procedure [if applicable]	Signature date	Amount (in EUR)
Accounting services (Back Office Arrangements in accordance with SBA Art. 13 for all JUs)	Service level agreement	EU-Rail	NA		NA
Accounts auditing services	Framework contract awarded by EU-Rail (Global Health EDCTP3 JU party to it based on SLA signed in the context of BOA for Accounting Services)	Baker Tilly Bedrijfsrevisoren		09/11/2023	1 454 000
Accounts auditing services	Specific contract	Baker Tilly Bedrijfsrevisoren	NA	21/12/2023	15 000
Catering services	Framework contract (BOA procurement for all JUs)	CIBACCO	Inter-institutional open tender	19/09/2023	900 000
Water supplies	Framework contract (BOA procurement for all JUs)	Aqua Vital	Negotiated procedure	30/08/2023	44 000
Coffee machine rental and coffee supplies	Framework contract (BOA procurement for all JUs)	Julius Meinl	Negotiated procedure	29/09/2023	131 000
Externalisation of data protection officer functions	Service level agreement with EU-Rail (to use specific contract implementing framework contract S2R.19.OP.02)	Privanot	NA	7/06/2023	193 200 (specific contract)
Managed IT services	Framework contract (BOA procurement for all JUs)	Inetum Realdolmen Belgium	Open procedure	17/01/2023	5 000 000



## 2.6. IT and logistics

The main goal of the Global health EDCTP3 JU IT office was to take concrete steps towards the JU's complete IT autonomy from the European Commission.

The Global Health EDCTP3 JU signed an SLA with DG DIGIT for the use of ICT Procurement and Cloud services and onboarded several inter-institutional Framework Contracts. The JU also decided to integrate the back-office arrangements for IT Services (BOA IT), whose implementation had been initiated in 2023 following the Article 13 of the SBA, and will be formalised in the course of 2024, allowing a smooth transition from the EC IT infrastructure to the one of the Joint Undertakings (having signed the SLA for the BOA IT).

Consequently, as part of the synergies with other JUs, the Global Health EDCTP3 JU onboarded a FWC for IT Managed Services for the JU's offices in the White Atrium building, thus joining a common effort on IT infrastructure and services. The Global Health EDCTP3 JU collaborated closely with the other JUs and provided its input on defining the BOA IT concept.

The JU also purchased laptops, displays and other IT equipment (printers and scanners) required for the staff, as well as corresponding software licenses to prepare its IT infrastructure autonomy.

During 2023, multiple other SLAs were signed for access to corporate IT systems, notably with DG HR for the access to various SYSPER modules (HR management), with PMO for MiPS (missions management) and RCAM/JSIS (sickness insurance scheme), and with DG BUDG for ABAC Accounting and Treasury services.

The Global Health EDCTP3 JU has fully onboarded the eGrants corporate tools (i.e., EMI, SyGMA, Compass) and taken steps towards the onboarding of the Document Management eco-system HAN/ARES.

The JU visual identity was defined with the help of a service provider and a website was designed and deployed at <https://globalhealth-edctp3.eu/>

For cybersecurity, the Global Health EDCTP3 joined the other JUs in signing an SLA with DIGIT and [CERT-EU](#).

## 2.7. Human Resources

From an HR perspective, the Global Health EDCTP3 JU was still in its start-up phase throughout 2023.

The Human Resources Manager took up duties in June 2023, taking over the activities previously covered by European Commission staff, notably unit RTD.D.1, DG HR and PMO.

### 2.7.1. HR Management

The recruitment of highly qualified staff to provide a solid basis for the new JU remained at the core of HR activities in 2023.

On 31 December 2023 the establishment plan was 57% fulfilled, with 11 Temporary Agents (TA) and 6 Contract Agent (CA) recruited. One external staff member was recruited to provide administrative support.

#### MAIN ACHIEVEMENTS IN 2023:

##### Recruitment

The intensive establishment of the organisational structure of the Global Health EDCTP3 JU continued, with the onboarding of key functions in addition to the initial staff:

- Human Resources Manager and IT, Scientific, Project, Legal, Governance, Budget, Communications Officers, Financial and Operations Assistants, Internal control and audit Manager.

The selection of the Executive Director was finalised, ensuring that the Global Health EDCTP3 JU could attain autonomy before the end of the year.

Three vacancy notices were further published, and the successful candidates were offered the positions before the end of the year:

- Head of Unit, Administration and Finance (Inter-agency and external selection);
- Personal Assistant to the Executive Director (external selection);
- Administrative Assistants for the Administration and Operations Units (external selection).

To gradually reach the target of 34 staff, seven reserve lists, including those established based on the eight vacancy notices published in 2022, were extended. The recruitment of the strategic management and coordination positions started, with the job descriptions for the Head of Operations and the

Strategic Partnerships and Communications Team Leader roles to be published in the first quarter of 2024.

The HR IT tool allowing autonomy in the selection process was successfully negotiated to be implemented early in 2024.

### **Personnel policies and procedures**

Specific HR policies were adopted:

- Duration and renewal of contracts for TAs and CAs;
- Recruitment policy and guidelines for the selection committees;
- Learning and Development covering initial staff trainings and;
- Setting up the staff committee: the first staff committee of the Global Health EDCTP3 JU was successfully elected and established in November 2023.

Templates and manuals were produced, after benchmarking other EU organisations, allowing for better harmonisation among the JUs, exploiting best practices and achieving efficiency gains.

The implementation of the HR IT tools system, Sysper, whose modules allow efficiency of document management, job quotas management, job descriptions and centralisation of personnel files was also achieved during 2023.

### **General Implementing Provisions of the Staff Regulations**

As an EU body, the Global Health EDCTP3 JU's main reference documents in terms of staff working conditions are the EU Staff Regulations and Conditions of Employment of Other Servants of the European Union (CEOS). The main legal texts in this area were adopted in 2022.

The Global Health EDCTP3 JU continued working on the completion of the legal framework applicable to its staff by developing implementing rules to these Staff Regulations. During 2023 the Governing Board adopted 14 new General Implementing Provisions (GIP) of Staff Regulations:

Staff Implementing Rules (SIR) implemented in 2023	
Title of the SIR	Reference and date of the GB decision
SIRs on Whistleblowing	12/2023 of 3 August 2023
SIRs on Harassment	13/2023 of 3 August 2023
SIRs on Learning and development	14/2023 of 3 August 2023
SIRs on Rules on Col staff	15/2023 of 3 August 2023
SIRs on Setting up a Staff Committee	16/2023 of 3 August 2023
SIRs on Administrative inquiries	17/2023 of 3 August 2023
SIR on AIPN (Art. 110)	33/2023 of 23 November 2023

Staff Implementing Rules (SIR) implemented in 2023	
Title of the SIR	Reference and date of the GB decision
SIRs on Reclassification of Temporary Agents	34/2023 of 1 December 2023
SIRs on Reclassification of Contract Agents	35/2023 of 1 December 2023
SIRs on Appraisal of Temporary Agents	36/2023 of 1 December 2023
SIRs on Appraisal of Contract Agents	37/2023 of 1 December 2023
SIRs on Adviser functions	38/2023 of 1 December 2023
SIRs on Unpaid leave	39/2023 of 1 December 2023
SIRs on Temporary occupation of management posts	40/2023 of 1 December 2023

### Probation period and Appraisal

Performance management tools, in which goals and development are defined, were put in place:

In 2023, 8 probation period reports were launched: all staff were confirmed in their functions, and the annual appraisal exercise was performed for 2 staff members.

### Training

The European Commission training catalogue was made accessible to the Global Health EDCTP3 JU staff through an SLA. Mandatory trainings for staff and senior management were organised:

- Prevention of harassment for Managers;
- Respect and dignity for staff;
- Anti-fraud.

Languages and core competencies courses, in particular for the use of Horizon Europe IT tools and financial management were used throughout the year.

The policy on learning and development will be amended over time to reflect the evolution of the JU.

### Contracts and Service Level Agreements (SLA) and Memorandum of Understanding (MoU)

Important SLAs / MoUs were signed 2023 to achieve efficiency gains and synergies:

- Back-Office arrangements: SLA with other Joint Undertakings established under the Council Regulation 2021/2085 (finalised, and expected for signature in 2024);
- Memorandum of Understanding with the European Commission for Learning and Development services, medical services, use of external staff;
- Agreement with OIB for logistic services (offices supplies, mail delivery, printing of business cards, access to CARES services).

## Wellbeing

Developing and fostering a corporate culture at the Global Health EDCTP3 JU was also a key for managing the growth of the JU. A special event for employees was held in December 2023 to bring staff together.

### 2.7.2. Efficiency gains and synergies

The Global Health EDCTP3 JU benefits from synergies with other joint undertakings, the Commission and EU agencies in order to procure goods and services. It has participated as contracting authority to several procedures led by other entities or became party to framework contracts already awarded when possible (see section 2.5). This enables the Global Health EDCTP3 JU to benefit from economies of scale and to obtain goods and services needed faster.

It concerns, among others, the office space needs of the Global Health EDCTP3 JU, which have been fulfilled in 2023 by way of an SLA with IHI Joint Undertaking so that the latter sub-leases office space to the Global Health EDCTP3 JU. Similarly, the Global Health EDCTP3 JU participated to a joint procurement procedure led by Clean Hydrogen JU with the purpose of ensuring office space for all joint undertakings based in Brussels as of 2025.

Part of these synergies have been implemented under back-office arrangements between joint undertakings, in application of Article 13 of the Founding Regulation.

## Context

Article 13 of the Single Basic Act identifies different areas in which Joint Undertakings may conclude service level agreements, subject to confirmation of viability and following screening of resources.

Since 2022 the JUs have considered to operate the following back-office arrangements:

AREA	CONTENT	LEAD JU
Accounting	Accounting Services	EU Rail JU
ICT	ICT services	Clean Hydrogen JU
HR	Common recruitment, HR Legal framework and HR digitalisation	CBE JU
Legal	Administrative procurements	Clean Aviation JU

Taking into consideration this approach, in 2023, back-office arrangements have been concluded in the following sectors for the Global Health ECTP3 JU:

- Accounting (lead: EU-Rail)
- Procurement (lead: Clean Aviation JU)

Further to the above, the JUs are currently working on establishing back-office arrangements in the area of Human Resources Support and IT.

### **Scope of the back-office arrangements for Accounting Services and activities carried out in 2023**

The JUs took over the Accounting Services that until 30 November 2022 were provided by DG BUDG and succeeded in implementing the BOA for Accounting Services in 2022, and immediately for the accounting closure 2022.

EU-Rail is the lead JU of this BOA and Accounting services are provided by 3 Accounting Officers coming from the following JUs: Clean Aviation JU, SESAR JU and EU-Rail JU.

#### **Organisation:**

- The Executive Director of the Lead JU is responsible for the organisation, oversight and coordination of the accounting services to the other JUs on the basis of an annex of the BOA SLA.
- The Head of Corporate Services or another officer with the necessary grade, skills and competencies of the Lead JU shall act as Accounting Coordinator of the BOA Accounting Officers.
- The Accounting Officer(s) of the JU Accounting Providers delivers the service to one or more JU Accounting Beneficiary and is responsible for the accounts she/he signs off, while counting on the support and coordination with the lead JU.

In order to ensure the provision of these services, it was agreed between the EC and the JUs to make use of the support of three additional Contractual Agents and of an external Accounting Services provider.

The BOA for Accounting Services are fully operational and are delivering the intended services, including the preparation of the Annual Accounts for ten Joint Undertakings. As of January 2024, the BOA team is composed of three Accounting Officers supported by three Accounting Assistants.

### **Scope of the back-office arrangements for Procurement and activities carried out in 2023**

To agree on the concept of the BOA Procurement, the Clean Aviation JU (CA JU) organised on the 7 October 2022 a 'BOA co-design Workshop' addressed to all JUs which expressed their interests in the BOA Procurement, presenting the concept and the principles of the cooperation.

This BOA has been established with the objective of centralising administrative procurement capability and process to maximise open tenders for award of inter-JUs FWCs and middle value negotiated procedures.

The concept was supported by the bi-annual Joint Public Procurement Planning reflecting the common needs identified by the Parties. On this basis a Service Level Agreement was drafted by the BOA Procurement Coordinator (CA JU) and following the conclusion of the consultation and approval by all the JUs is currently under the signature process.

The focus is on the critical joint administrative procurement such as ICT, building management/corporate services and common support services that will be identified and agreed via joint Public Procurement Planning (PPP).

### **Scope of the back-office arrangements for HR and activities carried out in 2023**

Human Resources Support among the areas where common back-office arrangements can be set up. In that respect, CBE JU took the lead with IHI JU for the establishment of the BOA HR. The BOA HR will implement actions in three main areas of HR Support: recruitment, HR legal framework and HR digitalisation.

Its objective is to maximise synergies among the JUs, harmonise procedures by adopting best practices, ensure coherent HR support services, achieve efficiencies and economies of scale, and increase the negotiation power of JUs operating under the SBA with contractors and service providers.

In line with the proposal of an enhanced coordination of the Network of JU HR officers, the conclusion of a Service Level Agreement (SLA) among the JUs was deemed necessary to ensure commitment to the execution of the BOA HR annual work plans.

In 2023, CBE JU and IHI JU led the discussions regarding the drafting of the SLA and organised several meetings with the participating JUs with a view to clarifying all possible questions and coming to an agreement. The SLA is expected to be signed in Q1 2024 and HR activities foreseen in the annual work plan to start in 2024 focusing on the three predefined areas of HR support.

In parallel, CBE JU launched the HR BOA collaborative platform (Teams) to allow exchange of information and documents such as templates library, minutes of the network meetings etc. among the HR officers inter-JU network.

In 2023, CBE JU along with other JU's also optimised efficiency gains and synergies by:

- sharing reserve lists to reduce time to recruit;
- providing expertise and resources allowing staff members to be panel members in several selection procedures of other JUs;
- supporting new Joint Undertakings during their onboarding/start-up phase providing guidance, advices and templates;
- organising training courses of general interest for all JUs (e.g. ethics and integrity, anti-fraud, respect and dignity at the workplace for JU managers);
- contributing to the development of a common HR legal framework among JUs by sharing ED and GB decisions on HR regulatory topics;
- supporting the communication campaign on the role of confidential counsellors and presentation of the newly appointed CCs to all JU staff members.

In 2023, the JUs, as inter-institutional partners, also attended meetings organised by the European Commission regarding the HR transformation programme that foresees the setting up of a new IT platform that will replace SYSPER.

In 2023, two new JUs implemented the e-recruitment tool "SYSTAL" resulting in a total of seven JUs using the same e-recruitment platform.

### **Scope of the back-office arrangements for IT and activities carried out in 2023**

The ICT area covers a list of ~50 services (service catalogue) structured in 6 service groups:

- Inter-JU IT Governance;
- Management of shared ICT infrastructure;
- Management of ICT tools, services and contracts;
- Workplace services provision;
- Security and compliance management;
- ICT activities specific per JU and not to be considered in scope of the BOA IT for the JUs.

The underlying concept is that, out of the ICT service catalogue, everything that is non-specific to a JU should be managed through the ICT BOA. Therefore, ICT developments and other activities specific to each JU will be under the responsibility of each Executive Director and will not be part of the ICT BOA, that in any case will have to ensure the integrity of the overall ICT architecture.

Following the formal proposal for BOA in the area of information and communication technologies sent by the Clean Hydrogen JU to the Executive Directors of the Joint Undertakings, on 20 December 2023, the Global Health EDCTP3 JU expressed interest in joining this BOA.



## 2.8. Data protection

In 2023, the Global Health EDCTP3 JU started its efforts to render its processes and working methods fully compliant with Regulation (EU) 2018/1725. The Global Health EDCTP3 JU, like other EU institutions, bodies, agencies and offices (EU institutions), processes personal data for a number of reasons (dealing with public requests for information, staff matters, procurement contracts, grant agreements etc.) according to the provisions of Regulation (EU) 2018/1725 on the protection of natural persons regarding the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

In 2023, the Global Health EDCTP3 JU has concluded an important part of its obligations based on the above Regulation.

Firstly, the Global Health EDCTP3 JU Executive Director has appointed a Data Protection Officer and a Deputy Data Protection Officer and communicated the appointment to the European Data Protection Supervisor.

Furthermore, the Global Health EDCTP3 JU has adopted the important documents below, following consultation of the European Data Protection Supervisor:

- a) The GB Decision GH-EDCTP3-GB/18/2023 on the Restrictions of the rights of the data subjects which was also [published on the Official Journal of the European Union – 16 October 2023](#), and
- b) the ED Decision GH-EDCTP3-ED/15/2023 on the DPO Implementing Rules.

Finally, the Public Central Register of the processing operations of the Global Health EDCTP3 JU was also finalised and [published on the JU's website](#). Staff members relevant to each of the processing operations were involved in the drafting and the revision of the Register, which also raised awareness inside the JU on matters of personal data protection. The DPO also presented the annual report on data protection during the Governing Board meeting that took place on 7 November 2023.

### 3. GOVERNANCE

### 3.1. Major developments

The Global Health EDCTP3 Joint Undertaking is a partnership between the European Union, represented by the European Commission, and the EDCTP Association, representing European and sub-Saharan African member countries participating in the partnership. On 31 December 2023, 15 European and 28 African countries were members of the EDCTP Association. The list of member countries of EDCTP Association can be found here: [Members of the General Assembly - EDCTP](#).

EDCTP was the first initiative receiving EU support based on Article 185 of the Treaty on the Functioning of the EU (ex-Art. 169), which allows the EU's participation in research programmes jointly undertaken by several EU countries. During its first programme (EDCTP1, 2003-2015), EDCTP operated as a European Economic Interest Grouping (EEIG) incorporated in the Netherlands, with its membership restricted to 16 countries in the European Economic Area. Based on the success of EDCTP1, the second EDCTP programme (EDCTP2) was launched in 2014, transitioning from an EEIG to an international Association under Dutch law, a construct that allowed the European Framework Programme for Research and Innovation (Horizon 2020) associated countries and sub-Saharan member states to become full members.

The Global Health EDCTP3 JU has been established by Council Regulation 2021/2085 of 19 November 2021 establishing the joint undertakings under Horizon Europe and operates in the frame of the Horizon Europe programme.

The governance structure of the Global Health EDCTP3 JU has been established in accordance with the Council Regulation where according to the relevant provisions, the bodies of the JU are:

- a) the Governing Board;
- b) the Executive Director;
- c) the Scientific Committee;
- d) the Stakeholders Group.

Following the establishment of the JU, its decision-making and advisory bodies have also been set up and were fully operational during 2023.

The year 2023 was undoubtedly marked by the challenge of achieving financial autonomy. The European Commission has supported the initial operation of the Global Health EDCTP3 JU until it achieved the operational capacity to implement its own budget. Together with the Executive Director ad interim and the JU's staff, the European Commission's Directorate-General for Research and Innovation (DG RTD) has carried out the necessary procedures in collaboration with the EDCTP Association to ensure that all requirements were fulfilled before financial autonomy.

Following the appointment of the Executive Director, Dr Michael Makanga, on 18 September 2023 and with his agreement, the interim Executive Director, Dr Nimmesgern, proposed the date of 23 November 2023 as the date on which the Global Health EDCTP3 JU would have the capacity to implement its own budget, i.e. the date of financial autonomy. This was done based on the content of the Readiness Assessment Report that provided the state of development of the requirements and criteria which were necessary for the Global Health EDCTP3 JU to demonstrate its financial autonomy. These requirements and criteria were developed by the European Commission services for judging the readiness for financial autonomy of other EU Bodies.

At its meeting of 7 November 2023, the Governing Board approved the Readiness Assessment Report and the proposed date of financial autonomy. On 23 November 2023, the Global Health EDCTP3 JU entered the next phase in its implementation, led by the new Executive Director, Dr Michael Makanga, who took up his duties on 16 November 2023. The Work Programme 2024, including all funding opportunities for the year to come was approved by the Governing Board and published a few weeks later.

### 3.2. Phasing-out plan monitoring

During its meeting in November 2023, the Governing Board held a first discussion on the phasing-out plan. Following this, the first version of the phasing-out plan has been prepared in late 2023 and adopted by the Governing Board on 24 January 2024 as a result of a written procedure launched on 21 December 2023. It is based on the template provided by the Commission to all Joint Undertakings and will be completed as planned by the end of 2024. This first version of the plan mainly focused on Chapter 5 of the Phasing-out plan – “Administrative and operational adaptations” for the phasing-out period in terms of legal status, staffing, accounting and cashflow, procurement, IT, logistics as well as follow up of grant agreement obligations after the end of projects.

### 3.3. Governing Board

The Governing Board is the decision-making body of the Global Health EDCTP3 JU. It has the overall responsibility for the strategic orientation, coherence with the relevant Union objectives and policies and operations of the JU and supervises the implementation of its activities.

Shortly after the establishment of the Global Health EDCTP3 JU, the Governing Board held its first meeting in January 2022 where its Rules of Procedure were adopted. It is composed of six representatives of the European Commission on behalf of the European Union and six representatives of the EDCTP Association. During 2023, the Chairperson was Dr Henning Gädeke (EDCTP Association) and the Vice-Chairperson was Ms Irene Norstedt (European Commission, RTD).

In 2023, the Governing Board was composed of:

Six representatives of the **EDCTP Association** (50% of the voting rights):

- Henning GÄDEKE, *Chairperson of the GB, Chair of the General Assembly and of the Board of the EDCTP Association, Division “Global and Public Health Research” at the German Ministry for Education and Research*
- Maria-Teresa BEJARANO, *Senior Research Adviser at Sida and Adjunct Professor of Infection Biology/Immunology, Vice-Chair of the General Assembly and of the Board of the EDCTP Association, Sida and Karolinska Institutet, Sweden*
- Godfrey BIEMBA, *Director and CEO, National Health Research Authority, Zambia*
- Eric D'ORTENZIO, *Head of Strategy and Partnerships Department, ANRS, France*
- Glaudina LOOTS, *Director for Health Innovation, Vice-Chair of the General Assembly and of the Board of the EDCTP Association, Department of Science and Innovation in South Africa*
- Samuel OKWARE, *Director-General, , Uganda National Health Research Organisation (UNHRO)*

Six representatives of the **European Commission** on behalf of the European Union (50% of the voting rights):

- Irene NORSTEDT, *Vice-Chairperson of the GB, Director, Directorate People: Health & Society, Directorate-General for Research and Innovation (DG RTD)*
- Maria Cristina RUSSO, *Director, Directorate International Cooperation, Directorate-General for Research and Innovation (DG RTD)*
- Pierre DELSAUX, *Director-General, Health Emergency Preparedness and Response Authority (HERA) until 30.09.2023 and replaced by Laurent MUSCHEL*
- Martin SEYCHELL, *Deputy Director-General, Directorate-General for International Partnerships (DG INTPA)*
- Kristin SCHREIBER, *Director, Directorate Ecosystems I: Chemicals, Food, Retail, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)*
- Isabel DE LA MATA BARRANCO, *Principal Adviser – Health and crisis management, Directorate-General for Health and Food Safety (DG SANTE)*

Alternate members of the Governing Board:

- Barbara KERSTIENS, *Head of Unit RTD.D1 – Combatting Diseases, Directorate-General for Research and Innovation (DG RTD)*
- Nienke BUISMAN, *Head of Unit RTD.F2 – International Cooperation Policy, Directorate-General for Research and Innovation (DG RTD)*
- Laurent MUSCHEL, *deputy Director-General, Health Emergency Preparedness and Response Authority (HERA) until 30.09.2023 and as 13.12.2023 of replaced by Wolfgang PHILIPP, Principal Adviser – Chief Science Officer, Health Emergency Preparedness and Response Authority (HERA)*

- Gabriella FESUS, *Head of Unit INTPA.G4 – Social Inclusion and Protection, Health and Demography, Directorate-General for International Partnerships (DG INTPA)*
- Giacomo MATTINO, *Head of Unit GROW.F3 – Food, Retail, Health, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)*
- Wojciech KALAMARZ, *Adviser on International Relations, Directorate-General for Health and Food Safety (DG SANTE).*

During 2023, the Governing Board held three meetings:

- on 10 March 2023 where the main agenda point was the approval of the Work Programme 2023 which was adopted a few weeks later by written procedure;
- on 18 September 2023 for the interviews of the shortlisted candidates for the post of the Executive Director, the selection and the adoption of the decision on the appointment;
- on 7 November 2023 at the side of the EDCTP Forum held in Paris where the main agenda points were the Work Programme 2024 and the adoption of the decision on the financial autonomy of the Global Health EDCTP3 JU.

In addition to the above, in 2023 the Governing Board adopted by written procedure several other important decisions related to inter alia:

- the selection of the members of the Stakeholders Group
- the appointment of the Accounting Officer of the JU;
- the Back Office Arrangement on accounting services, human resources and procurement;
- Staff Implementing Rules;
- the actions selected for funding from the HORIZON-JU-GH-EDCTP3-2023-01 Call for proposals
- amendments to Budget 2023;
- the Work Programme 2024.

The complete list of the decisions adopted by the Governing Board is available on the JU website: [Governing Board Decisions](#).

### 3.4. Executive Director

The Executive Director is the chief executive responsible for the day-to-day management of the JU managing the administrative, operational and financial measures necessary for the proper implementation of the annual work programmes and other budgetary and strategic decisions. The Executive Director is the legal representative of the Global Health EDCTP3 JU and is accountable to the Governing Board. He is supported in his activities by the staff of the Programme Office of the Joint Undertaking.

In 2021, the Commission designated Dr Elmar Nimmesgern, an experienced official of the European Commission, to act as interim Executive Director of the Global Health EDCTP3 JU until the Executive Director could take up his/her duties following his/her appointment by the Governing Board.

Dr Nimmesgern served as interim Executive Director up until 15 November 2023 and successfully led the Global Health EDCTP3 JU during the initial phase of its set-up and implementation and eventually to its financial autonomy.

On 18 September 2023, the Governing Board appointed Dr Michael Makanga as the first Executive Director of the Global Health EDCTP3 Joint Undertaking. The initial mandate of Dr Makanga started on 16 November 2023 for a period of four years. Dr Makanga has extensive experience in the global health research sector and was previously the Executive Director of the EDCTP Association.

During 2023, the interim Executive Director and the Executive Director took several important decisions, in complement to GB Decisions, such as the Implementation of financial circuits, the list of procedures, rules and frameworks adopted by the JU, the Data Protection Policy and the action plan for the Internal Control Framework of the JU. Further important decisions were taken related to the numerous recruitment procedures launched during the year (selection committees, reserve lists), the management of human resources (staff committee, recruitment policy, duration and renewal of staff contracts) and also the general administrative management of the JU Programme Office (appointment of staff members in key roles such as the Document Management Officer and the Data Protection Officer).

The Executive Director ensured a smooth communication and information flow between the JU Programme Office and all the bodies of the JU, the Governing Board, the Scientific Committee and the Stakeholders Group, attending all their meetings where he informed the members on the current activities of the JU and the status of the implementation of the work programme and the overall objectives.

As foreseen in the Council Regulation, throughout 2023 the Executive Director supported by the JU Programme Office, acted as the secretariat of the bodies of the Global Health EDCTP3 JU and provided organisational and administrative support to all three of them.

### 3.5. Scientific Committee

Constituted in 2022, the Scientific Committee is the scientific advisory body of the Global Health EDCTP3 JU. During 2023, the Committee was composed of 18 members coming from Europe and Africa, including a Chairperson (Professor John Gyapong) and a Vice- Chairperson (Professor Marleen Temmerman). Since its establishment, the Committee has been assisting the Global Health EDCTP3 JU in the design of the strategic and scientific activities, including the priorities to be addressed by the calls for proposals.

In the course of 2023, Scientific Committee Members met twice: on 30–31 May 2023 and 7 November 2023.

In May 2023, a discussion took place during a hybrid meeting about the research priorities to be addressed by the Work Programme 2024.

The second meeting, also hybrid, took place on 7 November 2023, alongside the 11th EDCTP Forum, with attendees present in Paris. During these meetings and further online interaction, SC Members have actively contributed to the prioritisation process for the Work Programme 2024, considering previous investments made through the Work Programme 2022 and the expected outcome from the Work Programme 2023.

Prior to submission of the Work Programme 2024 to the Governing Board for Approval, the Scientific Committee was consulted on the final content and on the EDCTP Association Members Additional Activities Plan annexed to the Work Programme.

### 3.6. Stakeholders Group

The Stakeholders Group (SG) was established in 2023 through two rounds of Calls for Expression of interest. Ten and twenty-three members were selected respectively after the first and second calls, with a balanced thematic, geographical and gender representation. A Chairperson and Vice-Chairperson have been elected, along with two representatives for the EDCTP Forum. Standard Operating Procedures have been agreed and notably the scheduling of three meetings per year, of which one hybrid alongside a major global health event in Europe or Africa, and the submission of an annual activity report to the Governing Board.

Inputs have been provided by the SG in line with the requirements of the Single Basic Act, and led to the following:

- 1) **Inputs to the EDCTP Forum:** two focal points within the group were involved in different activities such as the review of the Forum's abstracts and contributed to the design of the scientific programme;
- 2) **Revision of the SRIA:** a survey with overarching questions has been circulated and feedback has been requested on the potential need for a SRIA update: out of the replies received in 2023, 80% of participants recommended slight adjustments to the SRIA.

Strategic recommendations led to:

- a) a better prioritisation of topic calls and multi-annual planning;
- b) a more focused approach rather than the addition of new themes;
- c) the identification of initiatives which would work in synergy;
- d) the development of specific site readiness support for African Institutions to actively participate in all clinical stages of vaccine development and development of the EDCTP regional networks.



Funding recommendations led to the possibility of:

- a) longer-term (co)funding and portfolio funding;
- b) incentives to increase domestic resources for better sustainability;
- c) long-term investment in capacity development, and
- d) better alignment of ambitions with available funding.

Topic recommendations led to the possible:

- a) integration of health rights and equity;
- b) IPC/WASH (infection prevention and control/water, sanitation and hygiene);
- c) increasing support to Noncommunicable diseases (NCDs), STIs, hemorrhagic fevers, One Health and AMR;
- d) tackling co-infections as a topic rather than under a specific disease.

In addition, more attention to vaccine research, treatment and earlier stage research were recommended.

3) **Synergies with relevant adjacent sectors:** The first survey results recommended the increase of synergies with:

- a) the regulatory sector;
- b) commercial sector;
- c) patients' representatives;
- d) product development partnerships;
- e) major global health research funders (for joint investment in portfolio funding and large trials);
- f) technology and pharma industry;
- g) patients' representatives and viii) public/private partnerships. Requests were made to engage further communities/Civil Society Organisations (CSO)/Community Based Organisations (CBO), marginalised and disadvantaged communities.

4) In addition, recommendations have been provided regarding the Annual Strategic Research and Innovation agenda for 2025 with:

- a) overarching theme recommendations on health security, One Health/AMR, Health rights and equity, determinants of health, site readiness for vaccine testing in Africa and building on EDCTP2 projects and use of secondary data analysis;
- b) Disease prioritisation led – diarrheal diseases, lower respiratory tract infections, One Health and AMR, TB, Malaria and NTDs;
- c) In terms of research environment strengthening, recommendations led to the integration of clinical evaluations, earlier stages, establishment of clinical trial units in low-income countries, strengthening of regional networks and the inclusion of postdoc fellowships and early/mid-career research and follow-on career grants;
- d) Emphasis was also put on impact modelling, operational research, pharmacovigilance and implementation research;
- e) As for countermeasures to be supported, diagnostics with multiplex testing for key infectious diseases, treatments and preventive measures were recommended to be given more attention.

## 4. FINANCIAL MANAGEMENT AND INTERNAL CONTROL

This section reports on the control results and other relevant information that support management's assurance on the achievement of the financial management and internal control objectives. It provides information necessary to establish that the available evidence is reliable, complete and comprehensive. It covers all activities relevant to the Joint Undertaking.

## 4.1. Control results

This section assesses and reports the elements that support management's assurance regarding achievement of the internal control objectives: (1) effectiveness, efficiency and economy of operations, (2) reliability of reporting, (3) safeguarding of assets and information, (4) prevention, detection, correction and follow-up of fraud and irregularities, and (5) adequate management of the risks relating to the legality and regularity of the underlying transactions.

### 4.1.1. Effectiveness of controls

The effectiveness of the controls systems assessed is based on the legality and regularity of transactions, fraud prevention, protection and detection measures and the safeguarding of assets.

### 4.1.2 Legality and regularity of the financial transactions

The Global Health EDCTP3 JU uses internal control processes to ensure the adequate management of risks relating to the legality and regularity of the underlying transactions it is responsible for, taking into account the multiannual character of programmes and the nature of the payments concerned.

The Global Health EDCTP3 JU Financial Rules were adopted by Governing Board Decision on 3 May 2022 (Decision GH-EDCTP3-GB/22/2022). The Global Health EDCTP3 Financial Rules do not depart from the Commission Delegated Regulation (EU) 2019/887 of 13 March 2019 on the model financial rules for public private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046.

The Global Health EDCTP3 JU adopted a manual of financial circuits relating to the JU budget implementation on 25 October 2023. The financial circuits concern all financial operations considering the structure of the JU, any risk associated with the management environment and the nature of such financial operations. The financial circuits are established to standardise the mandatory steps of the processing of financial transactions and to clarify who the different actors are and their responsibilities (administrative and operational expenditure).

The general rule is that the main transactions, such as commitments and payments, are subject to a "standard" workflow composed of operational and financial initiating agents and operational and financial verifying agents before validation by the Authorising Officer.

Financial procedures in the JU are also based on the controls embedded in Commission tools. In Horizon Europe, reporting and validation of costs (including expert costs) is implemented using the European Commission IT tools such as SyGMA, COMPASS and EMI. In accounting, the controls are implemented using the accounting system ABAC.

The purpose of **ex ante controls** is to ascertain that the expenditure is in order and complies with the provisions applicable and the principle of sound financial management has been applied.

Ex-ante controls for Horizon Europe programme are implemented using the tools and methods used by the European Commission.

**Ex post controls** are an important tool to support management's assurance on the achievement of the financial management and internal control objectives.

Ex post controls of operational expenditure are implemented in line with the Audit Strategy of Horizon Europe which is an integral part of the overall Horizon Europe Control Framework. The audit strategy is carried out in close collaboration with the implementing services following the Horizon Europe governance working arrangements. Ex-post audits on beneficiaries of the Global Health EDCTP3 JU are carried out by the Common Audit Service (CAS) of DG Research and Innovation. CAS is responsible for implementing the audit strategy and carries out all audits for Horizon Europe (internally or outsourced to external firms).

In 2023, there were no ex-post audits for the Global Health EDCTP3 JU as the audit campaign for Horizon Europe has not been launched yet.

#### 4.1.3. Fraud prevention, detection, and correction

The Research and Innovation (R&I) family has established a common implementation approach for the prevention and detection of fraud in the framework programmes. The Global Health EDCTP3 JU alongside other entities implementing Research and Innovation Programmes share participants and face similar fraud patterns, making therefore the common approach more effective and efficient to coordinate anti-fraud activities. The Common Anti-Fraud Strategy in the research and innovation family was revised in 2023 and endorsed by the Horizon Europe Executive Committee on 22 December 2023. Accordingly, the Global Health EDCTP3 JU will launch the adoption by analogy of the Anti-Fraud strategy of the R&I family in 2024.

The Global Health EDCTP3 JU is represented in the Fraud and Irregularities in Research (FAIR) Committee. The FAIR Committee is the main forum of the R&I family on anti-fraud matters. It serves as a network to exchange information, experience and best practices.

In the course of 2023, the Global Health EDCTP3 JU anti-fraud measures focused on:

- awareness raising amongst staff on anti-fraud measures;
- joining the FAIR Committee in October 2023 and participating to FAIR meetings organised by DG R&I.

#### 4.1.4. Assets and information, reliability of reporting

The Global Health EDCTP3 JU currently manages assets via an Excel application, which is adequate for the small size of the inventory. Upon financial autonomy on 23 November 2023, onboarding into the corporate system ABAC Assets was not pursued as it was perceived as not cost effective for the remainder of 2023.

The assets reported by the Global Health EDCTP3 JU in the balance sheet 2023 mainly concern short term and long-term pre-financing paid before the financial autonomy and related to the first call launched by the JU in 2022.

On top of that, property, plant and equipment (PPE) and recoverables from non-exchange transactions (central treasury liaison accounts) were reported in the assets.

On 31 December 2023, the JU had no intangible assets and the tangible assets comprised new IT and communication equipment purchased before and after the financial autonomy.

The full amount of receivables relates to the entitlement of the JU over the cash held in the Commission's bank accounts as per the service level agreement for treasury services. The JU does not hold any form of cash or cash equivalents at hand or in accounts with financial institutions under its name.

#### 4.1.5. Efficiency of controls ("Time to")

The three efficiency indicators required by the Financial Regulation (FR) are time-to-pay [Article 116(1) of the FR], time-to-inform and time-to-grant [Article 194(2) FR]. Respectively, these indicators represent:

- Time-to-Inform (TTI) represents the time needed by the Global Health EDCTP3 JU to manage the evaluation and selection phase from the Call deadline to informing the participants;
- Time-to-Grant (TTG) represents the maximum of eight months between the call deadline and grant signature;
- Time-to-Pay (TTP) represents the outcome of the process for the payment of pre-financing to newly signed Grant Agreements and costs claimed by beneficiaries.

Following the launch of the call for proposals HORIZON-JU-GH-EDCTP3-2023-01 covering four topics for Research and Innovation Actions (RIA) and one topic for Coordination and Support Actions (CSA), we can currently report the following:

Indicator	Target	2023
Average Time to Inform (TTI)	153 days	133 days

The other efficiency indicators will be reported in the 2024 Annual Activity Report for the two calls for proposals launched in 2023.

#### 4.1.6. Economy of controls

The Global Health EDCTP3 JU acquired financial autonomy on 23 November 2023. Accordingly, costs of controls process was not performed in 2023.

## 4.2. Audit observations and recommendations

No audits were carried out in 2023, as the financial autonomy of the Global Health EDCTP3 JU was acquired on 23 November 2023.

### 4.2.1. Internal Audit

The **internal audit** functions of the Global Health EDCTP3 JU are carried out by the Internal Audit Service (IAS) of the Commission and by the **Internal Audit Capability** of the Global Health EDCTP3 JU, according to article 28 and article 30 of the Financial Rules (Decision GH-EDCTP3-GB/22/2022).

As the Global Health EDCTP3 JU has acquired autonomy in Q4 of 2023 (23 November 2023), no audits were carried out by the IAS in 2023. In 2024, the IAS will launch a risk assessment of all administrative, financial, operational and IT processes to serve as basis for their Strategic Internal Audit Plan (SIAP) that will identify audit topics for the period 2025-2027.

Based on the Council Regulation 2021/2085 establishing the Global Health EDCTP3 JU, and pursuant to Chapter 5 of the Global Health EDCTP3 JU Financial Rules, the JU established an Internal Audit Capability (IAC) adopted by the Governing Board decision (GH-EDCTP3-GB/25/2023 of 28 September 2023), which provides independent, objective assurance and consulting services designed to add value and improve the operations of the JU. Within the Global Health EDCTP3 JU, the Internal Audit Capability is performed by the Internal Control and Audit Manager (ICAM). The objective established for the Internal Audit Capability is to provide the Executive Director and the Governing Board with assurance as to the effectiveness and efficiency of risk management, control and governance process in the JU.

During 2023, the main activities of the ICAM focused on: firstly, ensuring compliance in internal control and audit required to achieving financial autonomy; and secondly, coordinating and supporting the launch of the first audits and work carried out by the European Court of Auditors, the Internal Audit Service and other stakeholders (i.e. external auditors and relevant Commission services).

#### 4.2.2. Audit of the European Court of Auditors

The European Court of Auditors (ECA), within their mandate, carries out an examination of the annual accounts and the underlying transactions for EU Joint Undertakings.

As required by Article 187 of the Treaty on the Functioning of the European Union (TFEU), ECA will audit the annual accounts of the Global Health EDCTP3 JU and the legality and regularity of the payments and revenue underlying the annual accounts for the first time following the financial autonomy of the JU (attained on 23 November 2023) in March 2024. Based on the results of the audit, ECA will provide to the European Parliament and the Council with a statement of assurance on the reliability of the JU's accounts and the legality and regularity of the underlying transactions.

In line with Articles 70(6) and 71 of the EU Financial Regulation<sup>7</sup>, the audit of the reliability of the accounts of the JUs is outsourced to independent audit firms and ECA reviews the quality of the work done by these external firms and obtains sufficient assurance so that they can rely on their work in formulating ECA audit opinions on the reliability of the JUs annual accounts for the specific year. In this regard, the annual accounts are audited by an external audit company (contracted through Europe's Rail Joint Undertaking framework contract on statutory audit services).

### 4.3. Assessment of the effectiveness of internal control (IC) systems

According to Article 36(2) of the EU Financial Regulation, the Global Health EDCTP3 JU, an entrusted body implementing EU budget, shall have a proper management and control mechanism in place. According to Article 36(2) of the EU Financial Regulation and Article 14 of the Global Health EDCTP3 JU Financial Rules, there is a need to implement and maintain an effective internal control system.

The internal control framework is designed to provide reasonable assurance regarding the achievement of the following five objectives: (1) effectiveness, efficiency and economy of operations, (2) reliability of reporting, (3) safeguarding of assets and information, (4) prevention, detection, correction and follow-up of fraud and irregularities, and (5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned.

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<sup>7</sup> Financial Regulation applicable to the general budget of the Union, July 2018. Regulation (EU, Euratom) 2018/1046 of 18 July 2018.

The priority objective is to implement and maintain an effective internal control system so that reasonable assurance can be given that resources assigned to the activities are used according to the principle of sound financial management and control procedures in place give the necessary guarantees concerning the legality and regularity of transactions.

#### 4.3.1. Continuous monitoring

The Global Health EDCTP3 JU Governing Board adopted the Global Health EDCTP3 JU Internal Control Framework (ICF) on 3 August 2023 (Decision GH-EDCTP3-GB/11/2023), whilst the operations of the JU were still covered by the organisational management and internal control system of the Research & Innovation Directorate-General of the European Commission until financial autonomy on 23 November 2023.

Based on the European Commission's framework of Internal Control, following the COSO 2013 Internal Control-Integrated Framework, the Global Health EDCTP3 JU has identified a set of 17 Internal Control Principles (ICPs) adapted to the environment of the Global Health EDCTP3 JU. These ICPs are based on the same principles as applied by the Commission. It provides generic management principles and sets out the minimum requirements for the Global Health EDCTP3 JU control activities.

The internal control framework for the Global Health EDCTP3 JU is built on:

- the implementation of the Internal Control Framework (ICF) offering at least equivalent guarantees to those of the Commission;
- procedures for selecting the best projects through independent peer review evaluation, and for translating them into legal instruments;
- project and contract management throughout the lifetime of every project;
- ex-ante checks on 100% of claims;
- ex post audits on a sample of claims as part of the Horizon Europe ex-post audits;
- scientific evaluation of project results.

Following the adoption of the ICF Decision by the Governing Board (Decision GH-EDCTP3-GB/11/2023), an action plan on the ICF was delivered. The action plan was the result of a gap analysis performed on the 17 principles of the ICF of the Global Health EDCTP3 JU. The objective of the gap analysis was to understand and assess if all principles of the ICF were (a) present and (b) functioning.

During the assessment, it was concluded that all principles are present and functioning and also identified some gaps.

Then, based on the gap analysis an action plan was prepared and validated by the Executive Director (Decision ED 22/2023). The timeframe for the actions to be implemented covers the period Q4 2023 to Q3 2024.



This action plan supports the Global Health EDCTP3 JU by facilitating the response to different types of risks and by providing reasonable assurance regarding the proper execution of the whole operational system.

The Global Health EDCTP3 JU has established a register of exceptions and non-compliance events to manage and monitor deviations from established processes and procedures. All deviations reported will be recorded in the register and analysed to identify any control failures.

Risks identified through the annual risk assessment exercise (described in the next section) were also assessed and managed through appropriate controlling and mitigating actions.

#### 4.3.2. Risk assessment and management

At the Global Health EDCTP3 JU, risk management is governed by:

- Article 19(4)(t) of Council Regulation (EU) 2021/2085, the Executive Director shall ensure that risk assessment and risk management are performed;
- Article 20 of the Global Health EDCTP3 JU Financial Rules: the Executive Director, in accordance with the minimum standards adopted by the Governing Board, puts in place the organisational structure and the internal control system having due regard to the risks associated with the management environment;
- Internal Control Principles No 6, 7, 8 and 9; Internal Control Framework of the Global Health EDCTP3 JU. Within this framework, the Executive Director assures the implementation of and compliance with the internal control principles supported by management and the Internal Control and Audit Manager.

A risk is defined as "Any event or issue that could occur and adversely impact the achievement of the Joint Undertaking's strategic and operational objective. Lost opportunities are also considered as risks".

The risk assessment aims to identify the main risks in achieving the objectives of the JU, analyse them and determine action plans on how they should be managed. All risks are captured in the Global Health EDCTP3 JU Risk Register, which provides for an evaluation of the risk level and description of the mitigating activities. The risk management aims to enable the organisation to fulfil its mission and objectives in the most efficient and effective way.

The annual risk assessment exercise took place between September and October 2023. The most significant risks were included in the Risk Register of the Global Health EDCTP3 JU. At JU level, the Risk Register documents the most significant risks and provides a record of risks and measures taken to manage them. The risks listed in the Risk Register are assessed in terms of impact and likelihood, mitigation actions proposed to reduce the probability of the risk materialising, or the severity of the

exposure should the risk occur, and owners identified with the JU. An action plan was put in place to address the identified risks and staff assigned to implement those actions.

The risks included in the Global Health EDCTP3 JU Risk Register are presented below:

Risk related to	Policy area & Activity/ Objective	Risk Description	Action Plan Summary – Brief description
Planning, processes & systems	IT & Other support systems	Access to information or impersonation of a staff member following a cyber-attack. Reputational, financial and operational damages.	Regular awareness of staff at least twice per year. Ensure staff follows the EC cybersecurity training.
External environment	Macro-environment	External events such as: epidemic or pandemic outbreaks; natural disasters; and/or political instability could negatively impact the successful completion of grants.	Epidemic or pandemic outbreaks: Potential mitigation actions include 1) the use of emergency funding mechanism where applicable, to allow the research community to carry out research response with outbreak- dedicated funding, 2) timely liaising with grant holders to ensure continuity of activities where possible.  Political instability: actions include agreeing with coordinators to suspend activities to protect project personnel and research participants; discussing with other EU bodies on the best ways to protect lives while ensuring continuity of activities, where possible.  Monitor regularly and actions to be taken if/when events occur.
External environment	External partners	Due to beneficiaries not fully familiar with Horizon Europe reporting rules, there can be errors in the reports leading to reporting of ineligible costs, resulting to financial loss for EDCTP3, reputational damages	Draft a plan on ex ante approach based on the risk of beneficiaries in the different phases of the Grant. Prepare a plan on how to train the JU staff to identify errors when applying the ex-ante checks. Organise workshops and any other interaction with beneficiaries, especially those with weak/insufficient financial and project management capacity.
Planning, processes & systems	IT & Other support systems	Fully onboarding IT systems like ARES, ABAC, eGrants are depending on a number of preliminary steps like purchasing M365 licenses and setting up new corporate email addresses and new EU logins	Mitigation: ensure business continuity using existing EU Logins.

### 4.3.3. Prevention of Conflicts of Interest

The JU Programme Office has developed a set of rules and procedures that are effectively implemented across its entire governance structure as follows:

- rules for the prevention and management of conflicts of interest of the Global Health EDCTP3 JU staff members (GH-EDCTP3-GB/03/2024).

In application of the GB decision, when joining the JU or after unpaid leave, each staff member signs a declaration of honour on the management of conflicts of interest;

- based on the same GB decision, for each recruitment procedure, both Selection Committee Members and candidates are required to declare any possible conflicts of interest by signing a declaration so that conflict of interests can be declared and potential adjustments made accordingly;
- evaluations by independent experts based on published selection criteria together with appeal mechanisms and full declarations of any interests, in application of Commission Decision C(2016) 3301;
- conflicts of interest rules for the members of the Governing Board (GB) and advisory bodies were renewed in January 2024 (GH-EDCTP3-GB/04/2024). This GB Decision, which repealed Decision GH-EDCTP3-GB/24/2022, addresses Governing Board members, members of the Scientific Committee and the Stakeholders Group and, where applicable, persons appointed to represent such members or their alternates; members of advisory or working groups set up by the Governing Board in accordance with Article 17(2)(x) of the Regulation; persons invited to attend meetings of the Governing Board or of any of the other bodies of the Joint Undertaking including observers; and other persons serving the Governing Board or the other bodies in whichever capacity. Every person concerned must sign a declaration of conflict of interest and a declaration of interest. The information contained in these declarations must be reviewed once a year.

A Governing Board decision on the code of Conduct applicable to the participants in the meetings of the Governing Board of the Global Health EDCTP3 JU was adopted in May 2022 (GH-EDCTP3-GB/23/2022). It requires participants to ensure the absence of conflict of interest.

Further, declarations of interests of Governing Board members must be submitted every year based on the GB's rules of procedure (GH-EDCTP3-GB/02/2022). These declarations as well as their declaration on confidentiality and conflict of interests are published on the JU's website.

#### 4.4. Conclusion on the assurance

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, all necessary control procedures are in place and working as intended, risks are being appropriately monitored and mitigated, and necessary improvements are being implemented. The Executive Director, in his capacity as Authorising Officer has signed the Declaration of Assurance.

## 4.5. Statement of Assurance

### 4.5.1. Assessment of the Annual Activity Report by the Governing Board

#### INTRODUCTION

In alignment with the multi-annual Strategic Research and Innovation Agenda, the key operational objectives of the Global Health EDCTP3 Joint Undertaking for 2023 were set out in the Work Programme (and its amendments) and included:

1. Advancing development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials, in SSA;
2. Strengthening research and innovation capacity and the national health research systems in SSA for tackling infectious diseases;
3. Facilitating better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment;
4. Strengthening capacity in SSA for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential;
5. Promoting productive and sustainable networking and partnerships in the area of global health research building North–South and South–South relationships with multiple private and public-sector organisations.

Besides the above, the following objectives were also set on the organisational side:

1. Continuation of the building up of the JU Programme Office;
2. Finalisation of the recruitment of the Executive Director;
3. Completion of set up for financial autonomy.

#### ANALYSIS

The Governing Board of the Global Health EDCTP3 Joint Undertaking has taken note of the Consolidated Annual Activity Report 2023 which was made available to the Board on 29 May 2024 and will be submitted for approval at its meeting on 27 June 2024.

The Governing Board is of the opinion that the Consolidated Annual Activity Report 2023 presents a true and fair view of the main activities of the JU in 2023, identifies the risks associated with the JU operations, duly reports on the use made of the JU resources provided and indicates the efficiency and effectiveness of the Global Health EDCTP3 Joint Undertaking's internal control system.

The Governing Board recognises the progress made by the JU towards the achievement of its objectives and notes in particular the following:

## 1. Implementation of the Annual Work Programme 2023

- the JU Programme Office concluded and signed grant agreements for the 28 projects funded under the Work Programme 2022 with a total funding of over EUR 103 million and the projects commenced their work during 2023;
- the Annual Work Programme 2023 was adopted in April 2023 with EUR 131,9 million in funding opportunities;
- the 2023 calls for proposals were launched with 7 topics to support research into infectious diseases;
- the evaluation of proposals for the calls 2023 was successfully executed;
- the successful selection of 27 proposals from the single stage topics 2023 with a total funding of EUR 78,2 million and the start of the grant agreement preparation;
- ensuring that all projects support South-South and South-North collaboration, having at least one partner from a European Union member state or country associated to Horizon Europe and at least one partner from a sub-Saharan African country, member of the EDCTP Association;
- maintaining a growing presence of the EDCTP programme in Africa through support to the activities implemented by the EDCTP Africa office, hosted by the South African Medical Research Council in Cape Town.
- ongoing efforts towards the establishment of coordination and cooperation mechanisms with the European Commission with the aim to promote knowledge sharing and synergies between the programmes;
- initiating the collaboration with potential contributing partners in order to achieve potential synergies and promote coordinated responses through joint calls of proposals;
- the EDCTP Association prepared and submitted a plan on the in-kind additional activities (IKAA) to be initiated in 2023 which foresees an estimated total value of over EUR 86 million;
- by the end of year 2023, the total estimated value of all initiated additional activities, which are mostly multi-annual, reaches over EUR 387 million;
- the commitment of the EDCTP Association to increasing its contribution to the Global Health EDCTP3 by at least EUR 110 million to reach a total contribution of at least EUR 550 million in anticipation of the UK association to Horizon Europe.

## 2. Support to Operations

- the focus of the communication activities on the establishment of new dissemination channels and tools with a new website, visual identity and social media accounts;
- the successful organisation of several specific events for the promotion of the JU funding opportunities and the raise of awareness about the partnership;
- the active presence of the Joint Undertaking at the Eleventh EDCTP Forum held in Paris from 7 to 10 November 2023;

- the promotion of the already funded projects and their results through specific news items and social media promotion;
- the adoption of several Governing Board and Executive Director decisions setting further the legal and financial framework of the Global Health EDCTP3 Joint Undertaking;
- budget execution after the financial autonomy reached 100% in commitment appropriations 47% in payment appropriations;
- the actions taken to achieve in 2024 the complete IT autonomy of the JU from the European Commission, with the conclusion of SLAs and contracts related among others to the use of procurement, ICT services and cybersecurity, the onboarding of the necessary corporate tools and IT systems;
- the recruitment of highly qualified staff in order to achieve the full establishment of the organisational structure of the Programme Office, the adoption of internal policies and procedures and general implementing provisions of the Staff Regulations;
- the participation of the Global Health EDCTP3 with the other Joint Undertakings to back-office arrangements in several areas, such as the accounting services, procurement and ICT services, in application of Article 13 of the Founding Regulation;
- the actions taken in the area of data protection towards the full compliance of the Global Health EDCTP3 with the Regulation (EU) 2018/1725, by appointing a DPO, adopting the necessary decisions and the finalisation and publication of the JU Public Central Register of the processing operations.

### 3. Governance

- the adoption of the first version of the phasing-out plan;
- the finalisation of the establishment of the governance structure of the Global Health EDCTP3;
- the smooth functioning of the Scientific Committee delivering scientific advice to the Joint Undertaking;
- the successful establishment of the Stakeholders Group leading to the appointment of 33 members;
- the effective coordination and collaboration of the two advisory bodies in order to ensure complementarities and pooling of knowledge.

### 4. Financial management and internal control

- the adoption of key decisions on the financial circuits, the Internal Audit Capability and the Internal Control Framework;
- the development of an action plan on the Internal Control Framework and a register of exceptions and non-compliance events;
- the annual risk assessment exercise leading to the development of the Risk Register with the related mitigation action plan;
- the establishment of rules and procedures on the prevention of conflict of interest via the adoption of the relevant decisions for the staff members and the members of the JU bodies.

## ASSESSMENT AND CONCLUSION

The declaration of the Executive Director and the Consolidated Annual Activity Report for 2023 give a good assessment (clear, unambiguous, congruous) of the operational and financial management in relation to the achievement of objectives, and the legality and regularity of the financial operations of the JU in the year 2023.

The Governing Board notes that the management of the Global Health EDCTP3 JU has reasonable assurance that, overall, all necessary control procedures are in place and working as intended, risks are being appropriately monitored and mitigated, and necessary improvements are being implemented.

The Governing Board notes that the Executive Director, in his capacity as Authorising Officer has signed the Declaration of Assurance without any reservation.

The Governing Board notes the progress made towards the establishment of the Global Health EDCTP3 Joint Undertaking governance bodies, its programme office and core processes.

The Governing Board notes the implementation of the Global Health EDCTP3 programme in alignment with the priorities set in the Strategic Research Agenda priorities, promoting the partnership among the research, innovation and global health stakeholders and the progress on the establishment of the JU as a global health funder.

Therefore, the Governing Board of the Global Health EDCTP3 JU hereby adopts this analysis and assessment of the Consolidated Annual Activity Report 2023 of the Authorising Officer. This analysis and assessment will be included in the Consolidated Annual Activity Report 2023.

Done at Brussels, on 27 June 2024

(signed)

For the Global Health EDCTP3 Joint Undertaking,

Irene Norstedt

Chairperson of the Governing Board



#### 4.5.2. Declaration of assurance

*I, the undersigned, Michael Makanga, Executive Director of the Global Health EDCTP3 JU*

*In my capacity as the authorising officer*

*Declare that to the best of my knowledge the information contained in this report gives a true and fair view.<sup>8</sup>*

*State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.*

*This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.*

*Confirm that I am not aware of anything not reported here which could harm the interests of the institution Global Health EDCTP3 JU.*

Brussels, 29 May 2024

(signed)

Michael Makanga

Executive Director

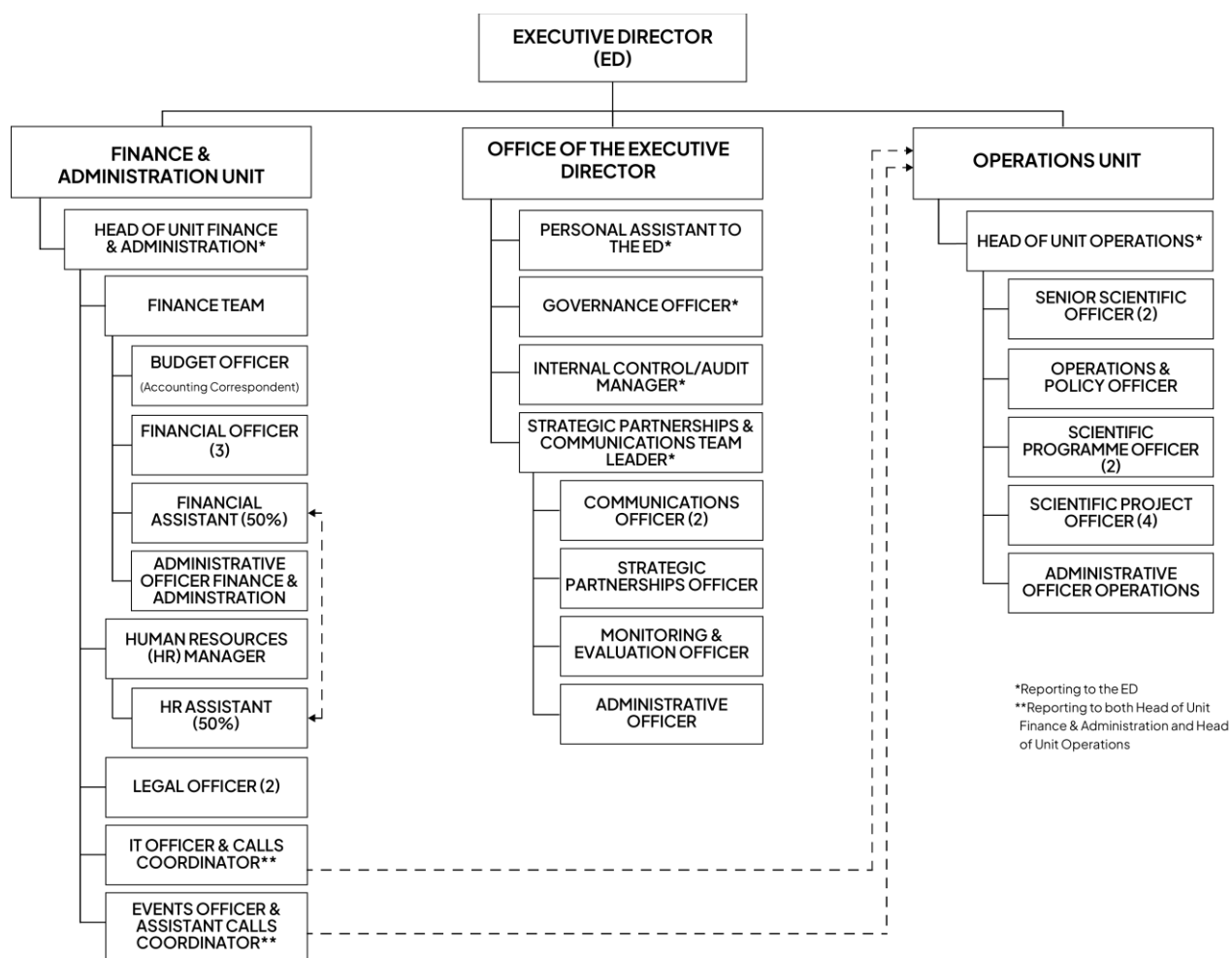
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<sup>8</sup> True and fair in this context means a reliable, complete, and correct view on the state of affairs in the Global Health EDCTP3 JU.

## 5. ANNEXES

## ANNEX 1. Organisational chart

The organisation chart of the Global Health EDCTP3 JU  
as to be adopted by the Governing Board on 27 June 2024



*Note: 1 Contract Agent FGIII post still to be allocated*

## ANNEX 2. Establishment plan and additional information on HR management

Staff Establishment Plan valid by the end of 2023

Function group and grade	2022				2023			
	Authorised		Actually filled as at 31/12/2022		Authorised		Actually filled as at 31/12/2023	
	Perm. posts	Temp. posts	Perm. posts	Temp. posts	Perm. posts	Temp. posts	Perm. posts	Temp. posts
AD 14	0	1	0	0	0	1	0	1
AD 12	0	2	0	0	0	2	0	0
AD 11	0	1	0	0	0	1	0	0
AD 8	0	3	0	0	0	5	0	0
AD 7	0	4	0	0	0	4	0	5
AD 6	0	3	0	0	0	5	0	2
AD 5	0	1	0	0	0	1	0	3
<b>TOTAL AD</b>	<b>15</b>				<b>19</b>		<b>11</b>	
AST 5	0	0	0	0	0	1	0	0
AST 4	0	1	0	0	0	1	0	0
AST 3	0	1	0	0	0	1	0	0
AST 2	0		0	0	0	0	0	0
<b>TOTAL AST</b>	<b>2</b>		<b>0</b>		<b>3</b>		<b>0</b>	
<b>TOTAL AD+AST</b>		<b>17</b>		<b>0</b>		<b>22</b>		<b>11</b>
<b>GRAND TOTAL (incl. CA)</b>	<b>23</b>		<b>0</b>		<b>30</b>		<b>17</b>	

Contract Agents	Authorised 2022	Actually filled as at 31/12/2022	Authorised 2023	Actually filled as at 31/12/2023
Function Group IV	3	1	4	4
Function Group III	3	2	4	2
<b>TOTAL</b>	<b>6</b>	<b>3</b>	<b>8</b>	<b>6</b>

## ANNEX 3. Publications from projects

In 2023, there were no publications reported from the currently active Global Health EDCTP3 projects.

*The following are the Scientific and policy publications related to the Global Health EDCTP3 IKA for the year 2023:*

Journal	Title	Authors	Publication Date	DOI
International Journal of Infectious Diseases	<a href="#">End of the Bedaquiline patent – a crucial development for moving forward affordable drugs, diagnostics, and vaccines for infectious diseases in low- and middle-income countries.</a>	Petersen E, Hui DS, Nachega JB, et al	2023-04-06	10.1016/j.ijid.2023.04.386
International Journal of Infectious Diseases	<a href="#">Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – a ten-year (2012–2022) global analysis of human and camel infections, genomic sequences, lineages, and geographical origins.</a>	Azhar, Esam I; Velavan, Thirumalaisamy P; Rungsung, Ikromi; Traore, Tieble; Hui, David S; McCloskey, Brian; El-Kafrawy, Sherif A; Zumla, Alimuddin	2023-03-28	10.1016/j.ijid.2023.03.046
Journal of Medical Entomology	<a href="#">The 2022 dengue outbreak in Bangladesh: hypotheses for the late resurgence of cases and fatalities.</a>	Haider, Najmul; Hasan, Mohammad Nayeem; Khalil, Ibrahim; Tonge, Daniel; Hegde, Shivanand; Chowdhury, Muhammad Abdul Baker; Rahman, Mahbubur; Hossain Khan, Manjur; Ansumana, Rashid; Zumla, Alimuddin; Uddin, Md Jamal	01/07/2023	10.1093/jme/tjad057
Viruses	<a href="#">Ecological Niche Modeling of Aedes and Culex Mosquitoes: A Risk Map for Chikungunya and West Nile Viruses in Zambia.</a>	Velu, Rachel Milomba; Kwenda, Geoffrey; Bosomprah, Samuel; Chisola, Moses Ngongo; Simunyandi, Michelo; Chisenga, Caroline Cleopatra; Bumbangi, Flavien Nsoni; Sande, Nicholas Chintu; Simubali, Limonty; Mburu, Monicah Mirai; Tembo, John; Bates, Matthew; Simuunza, Martin Chitolongo; Chilengi, Roma; Orba, Yasuko; Sawa, Hirofumi; Simulundu, Edgar	08/09/2023	10.3390/v15091900
Journal of Neurovirology	<a href="#">Characterizing Epstein-Barr virus infection of the central nervous system in Zambian adults living with HIV.</a>	Musukuma-Chifulo, Kalo; Ghebremichael, Musie; Chilyabanyama, Obvious Nchimunya; Bates, Matthew; Munsaka, Sody; Simuyandi, Michelo; Chisenga, Caroline;	30/10/2023	10.1007/s13365-023-01178-4

Journal	Title	Authors	Publication Date	DOI
		Tembo, John; Sinkala, Edford; Koralnik, Igor J; Dang, Xin; Chilengi, Roma; Siddiqi, Omar K		
PLOS Global Public Health	<a href="#">Current sampling and sequencing biases of Lassa mammarenavirus limit inference from phylogeography and molecular epidemiology in Lassa fever endemic regions.</a>	Arruda, Liã Bárbara; Free, Hayley Beth; Simons, David; Ansumana, Rashid; Elton, Linzy; Haider, Najmul; Honeyborne, Isobella; Asogun, Danny; McHugh, Timothy D; Ntoumi, Francine; Zumla, Alimuddin; Kock, Richard	08/11/2023	10.1371/journal.pgph.0002159
GigaByte	<a href="#">A dataset of small-mammal detections in West Africa and their associated micro-organisms.</a>	Simons, David; Attfield, Lauren A; Jones, Kate E; Watson-Jones, Deborah; Kock, Richard	04/12/2023	10.46471/giga byte.100
Immunity, Inflammation and Disease	<a href="#">Mucosal response of inactivated and recombinant COVID-19 vaccines in Congolese individuals.</a>	Mouzinga, Freisnel H; Heinzel, Constanze; Lissom, Abel; Kreidenweiss, Andrea; Batchi-Bouyou, Armel L; Mbama Ntabi, Jacques D; Djontu, Jean C; Ngumbi, Etienne; Kremsner, Peter G; Fendel, Rolf; Ntoumi, Francine	01/12/2023	10.1002/iid3.1116
Emerging Infectious Diseases	<a href="#">Laboratory Diagnosis of Mpox, Central African Republic, 2016-2022.</a>	Garba-Ouangole, Sandra; Bourner, Josephine; Mbenga, Festus; Gonofio, Ella; Selekon, Benjamin; Manirakiza, Alexandre; Kalthan, Ernest; Malaka, Christian; Boum, Yap; Olliaro, Piero; Nakouné, Emmanuel	12/07/2023	10.3201/eid2909.230514
Journal of the Pediatric Infectious Diseases Society	<a href="#">First-Line Antituberculosis Drug Concentrations in Infants With HIV and a History of Recent Admission With Severe Pneumonia.</a>	Chabala, Chishala; Jacobs, Tom G; Moraleta, Cinta; Ndaferankhande, John M; Mumbiro, Vivian; Passanduca, Alfeu; Namuziye, Natasha; Nalwanga, Damalie; Musiime, Victor; Ballesteros, Alvaro; Domínguez-Rodríguez, Sara; Chitsamatanga, Moses; Cassia, Uneisse; Nduna, Bwendo; Bramugy, Justina; Sacarlal, Jahit; Madrid, Lola; Nathoo, Kusum J; Colbers, Angela; Burger, David M; Mulenga, Veronica; Buck, W Chris; Mujuru, Hilda A; Te Brake, Lindsey H M; Rojo, Pablo; Tagarro, Alfredo; Aarnoutse, Rob E; EMPIRICAL clinical trial group	01/11/2023	10.1093/jpids/piad088
Journal of Acquired Immune Deficiency Syndromes	<a href="#">Brief Report: Suboptimal Lopinavir Exposure in Infants on Rifampicin Treatment Receiving Double-dosed or Semisuperboosted</a>	Jacobs TG, Mumbiro V, Chitsamatanga M, et al.	01/04/2023	10.1097/qai.0000000000003168

Journal	Title	Authors	Publication Date	DOI
	<a href="#">Lopinavir/Ritonavir: Time for a Change.</a>			
Journal of Infection	<a href="#">Clinical utility of C-reactive protein-based triage for presumptive pulmonary tuberculosis in South African adults.</a>	Calderwood, Claire J; Reeve, Byron Wp; Mann, Tiffeney; Palmer, Zaida; Nyawo, Georgina; Mishra, Hridayesh; Ndlangalavu, Gcobisa; Abubakar, Ibrahim; Noursadeghi, Mahdad; Theron, Grant; Theron, Grant; Gupta, Rishi K	12/11/2022	10.1016/j.jinf.2022.10.041
The Lancet Microbe	<a href="#">Xpert MTB/RIF Ultra on contaminated liquid cultures for tuberculosis and rifampicin-resistance detection: a diagnostic accuracy evaluation.</a>	Ghebrekristos, Yonas T; Beylis, Natalie; Centner, Chad M; Venter, Rouxjeane; Derendinger, Brigitta; Tshivhula, Happy; Naidoo, Selisha; Alberts, Rencia; Prins, Bronwyn; Tokota, Anitta; Dolby, Tania; Marx, Florian; Omar, Shaheed V; Warren, Robin; Theron, Grant	19/09/2023	10.1016/s2666-5247(23)00169-6
Journal of Clinical Microbiology	<a href="#">To Test or Not? Xpert MTB/RIF as an Alternative to Smear Microscopy to Guide Line Probe Assay Testing for Drug-Resistant Tuberculosis.</a>	Pillay, S; de Vos, M; Sohn, H; Ghebrekristos, Y; Dolby, T; Warren, RM; Theron, G	27/06/2023	10.1128/jcm.00017-23
The International Journal of Tuberculosis and Lung Disease : the Official Journal of the International Union Against Tuberculosis and Lung Disease	<a href="#">Continuous cough monitoring: a novel digital biomarker for TB diagnosis and treatment response monitoring</a>	Huddart S, Asege L, Jaganath D, et al.	01/03/2023	10.5588/ijtld.22.0511
Journal of Medical Case Reports	<a href="#">Incidental radiological findings during clinical tuberculosis screening in Lesotho and South Africa: a case series.</a>	Glaser, Naomi; Bosman, Shannon; Madonsela, Thandanani; van Heerden, Alastair; Mashaete, Kamele; Katende, Bulemba; Ayakaka, Irene; Murphy, Keelin; Signorell, Aita; Lynen, Lutgarde; Bremerich, Jens; Reither, Klaus	25/08/2023	10.1186/s13256-023-04097-4
Scientific Reports	<a href="#">COVID-19 screening in low resource settings using artificial intelligence for chest radiographs and point-of-care blood tests.</a>	Keelin Murphy, Josephine Muhairwe, Steven Schalekamp, Bram van Ginneken, Irene Ayakaka, Kamele Mashaete, Bulemba Katende, Alastair van Heerden, Shannon Bosman, Thandanani Madonsela, Lucia Gonzalez Fernandez, Aita Signorell, Moniek Bresser, Klaus Reither & Tracy R. Glass	11/11/2023	10.1038/s41598-023-46461-w
PLoS One	<a href="#">Implementation of the advanced HIV disease care package with point-</a>	Gils, Tinne; Kamele, Mashaete; Madonsela, Thandanani; Bosman, Shannon; Ngubane,	22/12/2023	10.1371/journal.pone.0296197

Journal	Title	Authors	Publication Date	DOI
	<a href="#">of-care CD4 testing during tuberculosis case finding: A mixed-methods evaluation.</a>	Thulani; Joseph, Philip; Reither, Klaus; Bresser, Moniek; Vlieghe, Erika; Decroo, Tom; Ayakaka, Irene; Lynen, Lutgarde; Van Heerden, Alastair		
BMJ Evidence-based Medicine	<a href="#">Piloting a new method to estimate action thresholds in medicine through intuitive weighing</a>	Jacobs BKM, Keter AK, Henriquez-Trujillo AR, et al	22/11/2023	10.1136/bmjebm-2023-112350
PLoS ONE	<a href="#">Evaluation of tuberculosis diagnostic test accuracy using Bayesian latent class analysis in the presence of conditional dependence between the diagnostic tests used in a community-based tuberculosis screening study</a>	Keter AK, Lynen L, Van Heerden A, et al.	02/03/2023	10.1371/journal.pone.0282417
Microorganisms	<a href="#">A Perspective on the Strategy for Advancing ETVAX®, An Anti-ETEC Diarrheal Disease Vaccine, into a Field Efficacy Trial in Gambian Children: Rationale, Challenges, Lessons Learned, and Future Directions.</a>	Hossain, M Jahangir; Svennerholm, Ann-Mari; Carlin, Nils; D'Alessandro, Umberto; Wierzbza, Thomas F	31/12/2023	10.3390/microorganisms12010090
Microorganisms	<a href="#">Prevalence of Diarrhoeagenic Escherichia coli among Children Aged between 0-36 Months in Peri-Urban Areas of Lusaka.</a>	Kapambwe Mwape, Samuel Bosomprah, Kennedy Chibesa, Suwilanji Silwamba, Charlie Chaluma Luchen, Nsofwa Sukwa, Cynthia Mubanga, Bernard Phiri, Mwelwa Chibuye, Fraser Liswaniso, Paul Somwe, Obvious Chilyabanyama, Caroline Cleopatra Chisenga, Monde Muyoyeta, Michelo Simuyandi, Tobias George Barnard, Roma Chilengi	17/11/2023	10.3390/microorganisms11112790
Frontiers in Immunology	<a href="#">Analyses of human vaccine-specific circulating and bone marrow-resident B cell populations reveal benefit of delayed vaccine booster dosing with blood-stage malaria antigens.</a>	Barrett, Jordan R; Silk, Sarah E; Mkindi, Catherine G; Kwiatkowska, Karolina M; Hou, Mimi M; Lias, Amelia M; Kalinga, Wilmina F; Mtaka, Ivanny M; McHugh, Kirsty; Bardelli, Martino; Davies, Hannah; King, Lloyd D W; Edwards, Nick J; Chauhan, Virander S; Mukherjee, Paushali; Rwezaula, Stella; Chitnis, Chetan E; Olotu, Ally I; Minassian, Angela M; Draper, Simon J; Nielsen, Carolyn M	24/03/2023 (preprint) published 17 January 2024	10.3389/fimmu.2023.1193079



Journal	Title	Authors	Publication Date	DOI
Wellcome Open Research	<a href="#">Safety and immunogenicity of varied doses of R21/Matrix-M™ vaccine at three years follow-up: A phase 1b age de-escalation, dose-escalation trial in adults, children, and infants in Kilifi-Kenya.</a>	Sang S, Datoo MS, Otieno E, et al	12/10/2023 (preprint only)	10.12688/wellcomeopenres.19795.1

## ANNEX 4. Patent from projects

No patents from projects in 2023 are to be declared.

## ANNEX 5. Scoreboard of Horizon Europe common Key Impact Pathway Indicators (KIPs)<sup>9</sup>

Not applicable.

<sup>9</sup> (based on Annex V to Regulation 2021/695/EU)

## ANNEX 6. Horizon Europe Partnership common Key Performance Indicators<sup>10</sup>

N°	Criterion addressed	Proposed common indicators	Baseline	Results for 2023	Target 2027
1	<b>Additionality</b>	Progress towards (financial and in-kind) contributions from partners other than the Union – i.e. committed vs. actual	2022	EUR 67 036 936:  - Uncertified reported IKAA (incurred)  <i>EUR 51 471 821 for Work Programme 2022</i>  - <i>Financial contribution from a contributing partner (included in a signed grant agreement)</i> <i>EUR 15 565 115</i>	EUR 800 000 000: - at least EUR 439 878 000 from member other than the Union - up to EUR 400 000 000 from contributing partners
2	<b>Additionality/ Synergies</b>	Additional investments triggered by the EU contribution, including qualitative impacts related to additional activities	2022	Not applicable	Not applicable
3	<b>Directionality</b>	Overall (public and private, in-kind and cash) investments mobilised towards EU priorities	2022	JU investment through grants (EU and contributing partner's financial contribution): EUR 118 655 738,75	1,6 billion
4	<b>International visibility and positioning</b>	International actors involved	2022	33 organisation members of the stakeholder group, of which 8 based in EU member states, 15 in SSA states and 10 in other states.	
5	<b>Transparency and openness</b>	Share & type of stakeholders and countries invited/engaged	2022	European Commission and EDCTP Association (private co-founder). The EDCTP Association is formed of 28 African Member States and 15 European countries (as of the 30 November 2023).	Expected contribution from the EDCTP Association: EUR 439 878 000 .
6	<b>Transparency and openness</b>	No and types of newcomer members in partnerships and their	2022	7 African Member States added in 2023 to the EDCTP Association: Liberia, Malawi,	

<sup>10</sup> (based on an interim report published on 21 June 2021 (Commission Experts' report, Section 5 and Appendix 1 <https://op.europa.eu/en/publication-detail/-/publication/6b63295f-d305-11eb-ac72-01aa75ed71a1/language-en/format-PDF/source-215872593> )

N°	Criterion addressed	Proposed common indicators	Baseline	Results for 2023	Target 2027
		countries of origin (geographical coverage)		Zimbabwe, Guinea-Bissau, Sierra Leone, Somalia, Benin.	
7	Transparency and openness	No and types of newcomer beneficiaries in funded projects (in terms of types and countries of origin)	2022	Not applicable	Not applicable
8	Coherence and synergies	Number and type of coordinated and joint activities with other European Partnerships	2022	Not applicable	Not applicable
9	Coherence and synergies	Number and type of coordinated and joint activities with other R&I Initiatives at EU /national/regional/sectorial level	2022	Not applicable	Not applicable
10	Coherence and synergies	Complementary and cumulative funding from other Union funds (Horizon Europe, National funding, ERDF, RRF, Other cohesion policy funds, CEF, DEP, LIFE, other)	2022	EUR 103 639 708,25 funding from Horizon Europe, EUR 18 520 602,92 euro from Melinda & Bill Gates Foundation	EUR 400 000 000 from contributing partners expected.
11	International visibility and positioning	Visibility of the partnership in national, European, international policy/industry cycles	2022	1 partnership – Melinda & Bill Gates Foundation for 2022 call on genomic epidemiology to expand the concept in Sub-Saharan Africa  Global Health EDCTP3 recognised with Prize for Global Health Diplomacy by the South African government.	

## ANNEX 7. Scoreboard of Key Performance Indicators specific to the Global Health EDCTP3 JU

JU-specific KPIs are currently being discussed with the Scientific Committee, in their advisory role, according to Article 19(4)(o) of the SBA. Once this process is completed, the Programme Office will be in the position to provide with the scoreboard, including units of measurement, baseline, results and targets.

Additional Activities scope	Additional Activities category	IKAA linked to Programme (PG) or Project (PJ)	Reported values 2022	Certified values 2022	Reported values 2023	Certified values 2023	Total reported values	Total certified values	Estimated planned values
Activities implemented by sub-Saharan African governmental research organisations	<ul style="list-style-type: none"> <li>1. Support to additional R&amp;I</li> <li>5. Training and skills development</li> <li>6. Contribution to the development of new standards, regulations and policies</li> <li>8. Communication, dissemination, awareness raising, citizen engagement</li> </ul>	PG	-	-	1 541 082,29	-	1 541 082,29	-	6 490 330,00
		PG	-	-	106 872,16	-	106 872,16	-	293 785,00
		PG	-	-	553 000,00	-	553 000,00	-	4 100 000,00
		PG	-	-	144 727,23	-	144 727,23	-	213 076,00
Activities of constituent or affiliated entities of the EDCTP Association aligned with similar activities from other constituent or affiliated entities of the EDCTP Association and independently managed in accordance with national funding rules	<ul style="list-style-type: none"> <li>5. Training and skills development</li> <li>6. Contribution to the development of new standards, regulations and policies</li> </ul>	PG	-	-	513 856,84	-	513 856,84	-	200 000,00
		PG	-	-	76 455,70	-	76 455,70	-	300 000,00
Activities which promote networking and partnerships building relationships with multiple private and public-sector organisations	<ul style="list-style-type: none"> <li>2. Scale-up of technologies</li> <li>5. Training and skills development</li> <li>6. Contribution to the development of new standards, regulations and policies</li> <li>7. Supporting ecosystem development</li> <li>8. Communication, dissemination, awareness raising, citizen engagement</li> </ul>	PG	-	-	4 725 000,00	-	4 725 000,00	-	29 000 000,00
		PG	-	-	6 041 561,53	-	6 041 561,53	-	11 989 321,00
		PG	910 800,00	-	1 071 500,00	-	1 982 300,00	-	1 808 000,00
		PG	17 761 888,00	-	25 296 931,30	-	43 058 819,30	-	74 379 580,00
		PG	30 000,00	-	-	-	30 000,00	-	80 000,00
Support for the development of research infrastructures such as clinical trial networks or cohorts related to the scope of the Global Health EDCTP3 Joint Undertaking, and support for strengthening health systems' preparedness for carrying out research activities within the scope of the Global Health EDCTP3 Joint Undertaking	<ul style="list-style-type: none"> <li>1. Support to additional R&amp;I</li> <li>2. Scale-up of technologies</li> <li>5. Training and skills development</li> <li>7. Supporting ecosystem development</li> <li>8. Communication, dissemination, awareness raising, citizen engagement</li> </ul>	PG	25 179 276,00	-	28 040 556,00	-	53 219 832,00	-	171 177 080,00
		PG	2 126 555,00	-	6 156 903,00	-	8 283 458,00	-	1 600 000,00
		PG	1 767 100,00	-	2 745 076,00	-	4 512 176,00	-	11 143 361,00
		PG	12 980 275,00	-	15 035 802,00	-	28 016 077,00	-	65 810 200,00
		PG	16 679,00	-	-	-	16 679,00	-	20 811,00
Grand Total			60 772 573	-	92 049 324	-	152 821 897	-	378 605 544

TOTAL IKAA 2022: BREAKDOWN PER COUNTRY	
Country	value (in EUR)
Belgium	7 435 791
France	6 687 557
Germany	18 226 323
Mozambique	116 679
Norway	726 978
Spain	443 000
Sweden	8 828 688
United Kingdom	18 307 557
<b>Total</b>	<b>60 772 573</b>

TOTAL IKAA 2023: BREAKDOWN PER COUNTRY	
Country	value (in EUR)
Belgium	6 244 379
France	6 052 170
Germany	41 495 508
Mali	118 370
Mozambique	100 000
Norway	653 402
Portugal	819 782
South Africa	828 724
Sweden	6 088 143
Uganda	6 887 149
United Kingdom	22 761 696
<b>Total</b>	<b>92,049,323</b>

TOTAL IKAA 2021-2023 (Evolution- Value in EUR)		
Planned IKAA (initiated in 2022 and 2023)	Reported IKAA with pending certification	Certified IKAA
387 605 544	152 821 896	0

## ANNEX 9. Final annual accounts (Optional)

### 9.1. Balance Sheet

31.12.2023	
<b>NON-CURRENT ASSETS</b>	
<i>Intangible assets</i>	-
<i>Property, plant and equipment</i>	26 015,58
<i>Pre-financing</i>	41 019 821,93
	<b>41 045 837,51</b>
<b>CURRENT ASSETS</b>	
<i>Pre-financing</i>	6 589 849,67
<i>Exchange receivables and non-exchange recoverables</i>	1 158 781,23
	<b>7 748 630,90</b>
<b>TOTAL ASSETS</b>	<b>48 794 468,41</b>
<b>CURRENT LIABILITIES</b>	
<i>Payables and other liabilities</i>	1 158 781,23
<i>Accrued charges and deferred income</i>	16 121 943,65
<b>TOTAL LIABILITIES</b>	<b>17 280 724,88</b>
<b>NET ASSETS</b>	
<i>Contribution from Members</i>	48 852 215,19
<i>Accumulated deficit</i>	-
<i>Economic result of the year</i>	(17 338 471,66)
<b>NET ASSETS</b>	<b>31 513 743,53</b>
<b>LIABILITIES AND NET ASSETS</b>	<b>48 794 468,41</b>

## 9.2. Statement of financial performance

2023	
<b>REVENUE</b>	
Revenue from non-exchange transactions	-
Recovery of expenses	-
Other	-
Revenue from exchange transactions	
Other	-
Total revenue	-
<b>EXPENSES</b>	
Operating costs	(16 570 466,65)
Staff costs	(201 870,00)
Other expenses	(566 135,01)
Total expenses	(17 338 471,66)
<b>ECONOMIC RESULT OF THE YEAR</b>	<b>(17 338 471,66)</b>

## 9.3. Cash flow statement <sup>11</sup>

2023	
Economic result of the year	(17 338 471,66)
Operating activities	<b>17 365 463,82</b>
Depreciation and amortization	976,58
(Increase)/decrease in pre-financing	(47 609 671,60)
(Increase)/decrease in exchange receivables and non-exchange recoverables	(1 158 781,23)
Increase/(decrease) in payables	1 158 781,23
Increase/(decrease) in accrued charges & deferred income	16 121 943,65
Increase/(decrease) in cash contributions	48 852 215,19
Investing activities	<b>(26 992,16)</b>
(Increase)/decrease in intangible assets and property, plant and equipment	(26 992,16)
<b>NET CASHFLOW</b>	<b>-</b>

<sup>11</sup> The treasury of the Global Health EDCTP3 JU is integrated into the Commission's treasury system. Because of this, the Global Health EDCTP3 JU does not have any bank accounts of its own. All payments and receipts are processed via the Commission's treasury system and registered on intercompany accounts, which are presented under the heading exchange receivables.



#### 9.4. Statement of changes in net assets

	Contribution from Members	Accumulated Surplus/(Deficit)	Economic result of the year	Net Assets
<i>Cash contribution</i>	48 852 215,19	-	-	48 852 215,19
<i>Unpaid cash contributions</i>	-	-	-	-
<i>Economic result of the year</i>	-	-	(17 338 471,66)	(17 338 471,66)
<b>BALANCE AS AT 31.12.2023</b>	<b>48 852 215,19</b>	<b>-</b>	<b>(17 338 471,66)</b>	<b>31 513 743,53</b>

## ANNEX 10. Materiality criteria

The ‘materiality’ concept provides the Executive Director with a basis for assessing the importance of the weaknesses/risks identified and thus whether those weaknesses should be subject to a formal reservation to his declaration. The materiality criteria are applicable to the Horizon Europe programme.

When deciding whether something is material, both qualitative and quantitative terms have to be considered.

In qualitative terms, when assessing the significance of any weakness, the following factors are considered:

- The nature and scope of the weakness;
- The duration of the weakness;
- The existence of compensatory measures (mitigating controls which reduce the impact of the weakness);
- The existence of effective corrective actions to correct the weaknesses (action plans and financial corrections) which have had a measurable impact.

In quantitative terms, to make a judgement on the significance of a weakness, the potential maximum (financial) impact is quantified.

## ANNEX 11. List of acronyms

Acronym/Abbreviation	Full title/Definition
AAP	Additional Activities Plan
Africa CDC	Africa Centres for Disease Control and Prevention
AMR	Antimicrobial Resistance
AUDA-NEPAD	African Union Development Agency-NEPAD
AVAREF	African Vaccine Regulatory Forum
CA	Contractual Agent
CAAR	Consolidated Annual Activity Report
CBO	Community Based Organisations
CHMP	Committee for Medicinal Products for Human Use
COVID-19	Coronavirus disease 2019
CSA	Coordination and Support Action
CSO	Civil Society Organisations
DG	Directorate-General
DG BUDG	Directorate-General for Budget
DG R&I	Directorate-General for Research and Innovation
DG RTD	Directorate-General for Research and Innovation
DNDi	Drugs for Neglected Diseases initiative
ECA	European Court of Auditors
ED	Executive Director
EDCTP	European and Developing Countries Clinical Trials Partnership
EDCTP AO	EDCTP Africa Office
EMA	European Medicines Agency
EU	European Union
FAIR	Fraud and Irregularity in Research
FR	Financial Regulation
GB	Governing Board
Global Health EDCTP3	Global Health EDCTP3 Joint Undertaking
HIV	Human immunodeficiency virus/acquired immunodeficiency syndrome
HR	Human resources
IHI	Innovative Health Initiative Joint Undertaking
JU	Joint Undertaking
IAC	Internal Audit Capability
IAS	Internal Audit Service
ICAM	Internal Control and Audit Manager

Acronym/Abbreviation	Full title/Definition
ICF	Internal Control Framework
ICP	Internal Control Principles
IT	Information and communication technology
IKAA	In-kind contributions to additional activities
IKOP	In-kind contributions to operational activities
IPC	Infection Prevention and Control
MMVC	Multi-Stage Malaria Vaccine Consortium
MoU	Memorandum of Understanding
NCDs	Noncommunicable diseases
NIDs	Neglected Infectious Diseases
NTDs	Neglected tropical diseases
OJ	Official Journal of the European Union
PPMT	Public procurement management tool
RIA	Research and Innovation Action
R&D	Research and Development
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2
SBA	Single Basic Act
SC	Scientific Committee
SDGs	Sustainable development goals
SG	Stakeholders Group
SIAP	Strategic Internal Audit Plan
SLA	Service-level agreement
SRIA	Strategic Research and Innovation Agenda
SSA	Sub-Saharan Africa
STIs	Sexually Transmitted Infections
TA	Temporary Agent
TB	Tuberculosis
TFEU	Treaty on the Functioning of the European Union
TTG	Time to Grant
TTI	Time to Inform
TTP	Time to Pay
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization
WHO-AFRO	World Health Organization African Region Office